Reference Manual

STAT PROFILE®
pHOx®

nova biomedical

EC Declaration of Conformity

Issued by

Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454, U.S.A.

Equipment Description:	Model - Stat Profile® pHOx® Analyzer Laboratory Equipment 100 - 120 / 220 - 240 V, 130 W, 50/60 Hz Protection Class I
Year of Manufacture:	See serial number showing date.
Applicable Directives:	73/23/EEC, Low Voltage Directive Laws for electrical equipment within certain voltage limits 89/336/EEC, EMC Directive Laws relating to electrical magnetic compatibility
Applicable Standards:	EN 61010-1/A2:1995, EN 61010-2-010/A1:1996 Equipment for Measurement, Control and Laboratory use EN 50081-1:1992 Electromagnetic Compatibility. Generic Emission Standard EN 50082-1:1992 Electromagnetic Compatibility. Generic Immunity Standard
Type Examination Certificate:	GS-mark License Number AL 01 06 20747 011 TUV Product Service, Munich/Germany

Authorized by : _____ **3/15/99**

Francis C Manganaro — Date
President
Nova Biomedical Corporation

Nova Stat Profile® pHOx® Reference Manual

Part Number and Ordering Information

The *Stat Profile® pHOx® Reference Manual* (PN 22363) can be ordered from Nova Biomedical Order Services. Write or call:

Nova Biomedical
200 Prospect Street
Waltham, MA 02454-9141
U.S.A.

Telephone: 1-800-458-5813

FAX: (781) 893-6998 (in the U.S.A.) or
(781) 899-0417 (outside the U.S.A.)

Technical Assistance

For technical assistance, call Nova Biomedical Technical Services at:

Telephone: 1-800-545-NOVA or
(781) 894-0800

FAX: (781) 894-0585

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The Stat Profile pHOx Analyzer is covered by the following patents:
U.S. Patent No. 4,686,479, U.S. Patent No. 5,578,194.

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Note: U.S. Legislative Requirements — Nova Analyzers

The new legislative requirements for clinical laboratories have established a new regulatory environment and have changed the responsibility that Nova Biomedical has regarding the proper operation and control of Nova analyzers. With the advent of the requirements that the end user specifically follows **all** directions for use from the manufacturer, Nova becomes a partner with the user and becomes responsible for providing instructions that will virtually guarantee that the analyzer is in control. This requires Nova to provide instructions on maintenance and control which are virtually foolproof in regards to assuring that an analyzer is in control.

In addition to asking that all operators perform the maintenance and calibration procedures described in this manual, we also recommend that **only** Nova reagents, calibrators, cleaning agents, and controls be run through the analyzers. These are the **only** materials that we have fully characterized and tested. We have neither tested the performance nor determined the long term effects of products provided by others for use on our instruments. Confirming that an analyzer is in control by using reagents and controls not certified by Nova Biomedical can not be guaranteed by Nova, and Nova will not be responsible for the consequences. Users who elect to use reagents, standards and/or controls from other producers should confirm by the appropriate testing protocols from those other manufacturers that Nova's instrumentation is in control and in compliance with all legislative requirements. This testing verification should also include a means of troubleshooting when the instrument is not in control, since Nova Biomedical cannot, in the present environment, provide that service. Since Nova Biomedical does not know the formulations of the reagents and controls used by other manufacturers, including the levels of surfactants, preservatives, viscosity adjusters, and other additives that may be used, there is no way for Nova to be certain that the results obtained on controls or patient samples will be correct when these products are used. There is also no way to tell whether there will be long term or short term adverse effects on sensor performance, sensor life, tubing or flow cell degradation, or on data quality/accuracy or reliability.

Nova Biomedical manufactures totally integrated systems to assure proper analyzer performance. We cannot characterize all products that might be used on Nova analyzers, nor can we control changes that other manufacturers might choose to make to their products. Therefore, use of these products with a Nova analyzer must be the responsibility of the individual end user and of that manufacturer rather than Nova.

Under these new legislative requirements, user modification of an *in vitro* diagnostic device, is also regulated. Modification of the product includes use of untested products or products which have not been tested to determine substantial equivalency and safety and effectiveness in use with Nova analyzers.

Nova Biomedical's Reference Manuals include the specific information needed for the proper maintenance, qualification, and operation of Nova Biomedical Analyzers. If the user follows the directions in those manuals, they should have very few problems. In the case where they need assistance from Nova Biomedical in troubleshooting their systems, we will stand ready to assist them in any and all ways necessary.

Cross-Reference Table for NCCLS Guideline

	NCCLS Guideline	Stat Profile pHOx Reference Manual
1.	Principle of Test	Appendix B: Sections B.2 to B.2.6
2.	Specimen required	Chapter 1, Sections 1.3, 1.3.1, 1.3.2
3.	Reagents, Standards, and Controls	Appendix A: Sections A.2 to A.2.3.1
4.	Calibration procedures and schedule	Chapter 3: Sections 3.16, 3.16.1 to 3.16.4
5.	Step-by-Step Directions	
	Analysis	Chapter 3: Sections 3.18, 3.18.1 to 1.18.4
	Maintenance	Chapter 4
	Troubleshooting	Chapter 5
6.	Calculations	Appendix B: Sections B.3 to B.3.2
7.	Frequency, Control Tolerance	Chapter 3: Sections 3.17, 3.17.1, 1.17.2
8.	Expected values	Appendix A: Section A.3
9.	Linearity limits	Appendix A: Section A.1
10.	Limitations (interferences)	Chapter 1, Sections 1.3.2, 1.3.3, 1.3.4
11.	References	Chapter 1: Page 1-3; Appendix B: Page B-9
12.	Effective Date	Table of Contents
13.	Distribution	Nova pHOx Customers
14.	Author	Alan J. Mannarino

NOTE: *This manual complies with the NCCLS guidelines Vol. 4, Section 2.1. As a user, you can copy and compile these above sections into one compact NCCLS Nova pHOx Manual or use the cross-reference to find the appropriate section in the Nova Stat Profile pHOx Reference Manual.*

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1 Introduction

This manual provides all necessary instructions for the routine operation and maintenance of the Stat Profile pHOx Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Stat Profile pHOx Analyzer.

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, capillary adapter, probe, sensor module, etc.) with care. Gloves and protective clothing are recommended.

NOTE: *This International Caution Label appears on the rear of the pHOx Analyzer and means refer to the manual.*

This section introduces the Stat Profile pHOx Analyzer and covers requirements, tests performed, procedural limitations, clinical utility, and sample handling.

1.1 Installation

This section covers the installation requirements and assembly procedures for the Stat Profile pHOx Analyzer.

> ***NOTE:*** *Under the Warranty, a Nova service representative will install this equipment for you.*

1.1.1 Requirements

Working Area Requirements:

Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes. Ambient operating temperature is 15 °C to 30 °C (59°F to 86 °F). Operate at humidity of 0 to 95% without condensation.

Electrical Requirements:

A grounded, 3-wire receptacle within 5 feet of the system is required for operation. The U.S. models require a 120 Volt AC line at 50/60 Hz frequency. The analyzer can be operated at 100 - 120; 220 - 240 Volt AC 50/60 Hz.

Fuse requirements:

- 2 Amp Time Delay (SB 2A or T2A) at 100 - 120 Volt AC line.
- 1 Amp Time Delay (T1A) at 220 - 240 Volt AC line.

1.2 Intended Use, Tests Performed, and Clinical Utility

Intended Use

The Stat Profile pHOx Analyzer is intended for *in vitro* diagnostic use by health care professionals in the quantitative determination of pH, PCO_2, PO_2, oxygen saturation (SO_2%), hematocrit (Hct), hemoglobin (Hb) in heparinized whole blood.

Measured Parameters

pH, PCO_2, PO_2, SO_2%, Hct, (Na^+ required for Hct), Hb, and barometric pressure

Calculated Parameters

From the directly measured results, the calculated results are

- Base Excess of the blood (BE-b)
- Base Excess of extracellular fluid (BE-ecf)
- Bicarbonate level (HCO_3^-)
- Standard Bicarbonate Concentration (SBC)
- Total Carbon Dioxide (TCO_2)
- Oxygen Content (O_2Ct)
- Oxygen Saturation (SO_2%) - (If measured result not available)
- Alveolar Oxygen (A)
- Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)
- Arterial Alveolar Oxygen Tension Ratio (a/A)
- Oxygen Capacity (O_2Cap)
- Hemoglobin (Hb_c) - (If selected or measured result not available)
- $P50$ (measure single point)
- pH, PCO_2, PO_2 (corrected to patient temperature)
- $\dot{Q}sp/\dot{Q}t$ (physiological shunt - requires 2 samples: mixed venous and arterial)
- Respiratory Index (RI - uses entered %FIO_2 or default value of 20.9)
- PO_2/FIO_2 ratio

With the Nova CO-OXIMETER inputs of Oxygen Capacity of hemoglobin (O_2Cap) and Oxygen Content of hemoglobin (O_2Ct), the additional combined CO-Oximeter/Stat Profile pHOx calculated results are

- CcO_2
- CaO_2
- $C\bar{v}O_2$
- $a\bar{v}DO_2$
- $P50$

Test Dependencies

- If O_2Cap from the Nova CO-OXIMETER is available, that value is displayed.
- If O_2Ct from the Nova CO-OXIMETER is available, that value is displayed instead of the calculated O_2Ct value.
- If SO_2% from the Nova CO-OXIMETER is available, that value is displayed instead of the SO_2% measured by the reflectance method.
- If Hb from the Nova CO-OXIMETER is available, that value is displayed instead of the Hb measured by the conductivity and photometric methods.

Clinical Utility[1]

The following list includes the clinical utility information for each of the analytes measured on the Stat Profile pHOx Analyzer.

Blood Gases: (PCO_2, PO_2, and pH)	Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases.
Oxygen Saturation	Used to assess the oxygenation of hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Also used in the diagnosis and treatment of cyanosis.
Hematocrit	Whole blood measurement of hematocrit is used to estimate that red blood cells are present in sufficient quantity to carry oxygen and carbon dioxide.
Hemoglobin	Oxygen is carried from the lungs throughout the body by hemoglobin present in red blood cells. Measurement of hemoglobin provides the clinician with information regarding the evaluation of chronic and acute anemias and also with information pertaining to the potential oxygen transport capability of the hemoglobin.
Physiologic Shunt	The physiologic shunt or AV Shunt calculation relates to the small fraction of the cardiac output which goes to the lungs that does not come into contact with oxygen exchange units (alveoli). In health, this shunt fraction is less than 5%. Increased shunt fraction is seen in cases where there is a pathophysiologic process that reduces the number of functional gas exchange alveoli or blood is directed away from functional alveoli.

Ref. 1.Tietz, N.W. ed. 1986. *Textbook of Clinical Chemistry*. W. B. Saunders Co.

1.3 The Sample

Sodium or lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes can be used on the Stat Profile pHOx Analyzer. The sample size is 70 µL for normal mode and 45 µL for micro mode (blood gases only).

1.3.1 Handling Requirements

Correct sample handling is critical to ensure that the blood gas values obtained accurately reflect the *in vivo* state. Ensure that all samples have been obtained and stored following consistent, clinically accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample within 15 minutes for blood gases. Storing samples on ice is not recommended. Using iced samples may elevate the PO_2 result.[1]

1. National Committee for Clinical Laboratory Standards. *Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes, and Related Analytes in Whole Blood; Proposed Guideline.* NCCLS Document C32-P. Vol. 13, No. 17.

1.3.2 Acceptable Anticoagulants

Sodium and lithium heparin are the recommended anticoagulants for use with the Stat Profile pHOx Analyzer. EDTA, citrate, oxalate, or sodium fluoride are not recommended for use.
Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, heparin concentrations of 20 I.U. per mL to over 100 I.U. per mL may be obtained. Liquid heparin when present in excess may cause errors by dilution in pH, PCO_2, and PO_2.
Our experience suggests that lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable in the critical care laboratory. Stat Profile pHOx Analyzer users should take careful note of these considerations when establishing reference intervals and interpreting results.

1.3.3 Interfering Substances

SO_2% Interferences:
High levels of COHb and MetHb will increase the reported SO_2% value.
MetHb values above 15% will interfere with the SO_2% value.
10% Intralipid solutions will interfere with the SO_2% when the blood concentrations of Intralipid are >500 mg/dL.
Hemolyzed samples will interfere with the SO_2% value.

Hematocrit (Hct) Interference:
White Blood Count (WBC) greater than 50,000 WBC/µL may increase the hematocrit value.

1.3.4 Matrix Effects

Nova instruments are designed for clinical environments to analyze actual patient specimens, not modified blood samples. Specimens removed from the patient, anticoagulated appropriately, and promptly analyzed are the only type of sample where the measurement results will be reliable. Matrix effects/interferences can occur when patient specimens are removed from the body, modified and then measured on a Nova instrument. For example, matrix effects have been seen on Nova analyzers when attempting to analyze samples collected from cell savers used in various surgical procedures. Also, evaluation laboratories run specimens from patients with a wide variety of pathologies and from patients who are being treated with a broad spectrum of therapeutic and pharmacological agents. Despite extensive clinical trials, it is not possible to anticipate every possible combination of transfused blood products, crystalloids, and drugs (or their metabolites) that may be present in a blood sample. As a result, some users have found that their particular patient mix has necessitated making adjustments to maintenance. For example, a high number of cardiopulmonary bypass pump or ECMO (extracorporeal membrane oxygenation) samples result in a need for increased analyzer maintenance. If you are experiencing excessive downtime, you may need to modify your own maintenance schedules. Nova's Clinical Applications Group will assist you in tailoring a maintenance program to meet these needs.

1.4 About This Reference Manual

This manual is for Stat Profile pHOx Analyzer.
Throughout this manual, *NOTE:* indicates especially important information, ***CAUTION:*** indicates information that is critical to avoid instrument damage or incorrect results, and ***WARNING:*** indicates possible hazard to the operator.

2 Setup

This section describes how to setup the Stat Profile pHOx Analyzer.

2.1 Installing the Stat Profile pHOx

The analyzer is initially installed by a factory authorized representative.

CAUTION: *The pHOx analyzer is designed to be left on with adequate fluids at all times. This is necessary to prevent crystallization of salts in the fluid lines and cuvette. If it is to be shut down indefinitely, purge all fluid lines with distilled water and then with air. The purge sequence is selected from the Operational Menu.*

2.2 Power Up Procedure

After power up, the analyzer checks the error condition status of the instrument by the Power On Self Test (POST). The bicolor LED on the front panel will be a solid yellow if the analyzer has passed this test.

NOTE: *After power up, the analyzer displays the pHOx logo screen. In less than 1 minute, the Not Ready screen will appear with the LED at solid yellow. The analyzer will need to be calibrated.*

2.3 Using the Keypad and Display

Overview The keypad, display, and status lights are located on the front panel.

Display The display provides prompts, menus, status information, error messages, patient results, etc. The top line gives the screen's name (i.e., Setup Menu) and in some screens the date and the time. The second line displays directions for the screen or additional information about the displayed data. The middle of the screen is for the menu items that you can select, detailed direction for procedures, patient information, or electrode statuses. The bottom line defines the soft keys.

Soft Keys

The 4 soft keys are defined by the labels currently shown on the lower line of the display. The keys cause system action, such as selection of menus, initiation of maintenance procedures, and other displays.
Some common soft keys are
Home returns you back to the READY screen.
Next Screen moves you to the next screen in the sequence.
Cancel returns to the previous screen or cancels a sequence.

Status Lights

The 2 status lights on the front panel reveal the system status as follows:
Steady Green - All air detectors and one or more channels are calibrated. The analyzer is ready for analysis or input.
Flashing Green - All air detectors and one or more channels are calibrated, but the analyzer is busy analyzing, priming, accepting external data, etc. The analyzer will not allow any analytical or any other sequence to be started until it becomes not busy.
Steady Yellow - One or more air detectors or all channels are not calibrated.
Flashing Yellow - One or more air detectors or all channels are uncalibrated and the analyzer is busy.

Status Symbols

There are a number of symbols that can appear after the results. The symbols have the following meanings:
↑ **(single up arrow),** ↓ **(single down arrow)** - The result is higher or lower that the defined reference range for the parameter.
↑↑ **(double up arrow),** ↓↓ **(double down arrow)** - The result is higher or lower that the defined alert range for the parameter.
↑↑↑ **(triple up arrow),** ↓↓↓ **(triple down arrow)** - The result is out of the analyzer's operating range.
X (an A through an analyte prefix) - The channel is uncalibrated.
? (question mark) - Insufficient sample is detected during sample reading.
*** (asterisk)** - The result is calculated using a default sodium concentration.
— (a line through an analyte prefix) - The channel did not pass QC and QC lockout is enabled; or the results have been suppressed.

Keypad

The keypad allows you to enter information into memory. It consists of 12 number keys (including a decimal point key and a dash key), up (↑), down (↓), left (←), and right (→) arrow keys, and an ENTER (↵) key. The arrow keys move the cursor on the display. Also, the left arrow key can be used as a backspace when entering numerical information. The ENTER (↵) key places data on the display into memory.

Analyze Keys

There are 2 keys to initiate an analysis: one key has an icon of a capillary tube and the other key has an icon of a syringe. To perform an analysis with a capillary sample, press the capillary key. To perform an analysis with a syringe sample, press the syringe key. These 2 keys are only active when the Home screen or the Result screen are displaying.

2.3.1 General Keypad Entry

Entering numbers:

1. In general, press the arrow keys to select a character entry field or option. Then follow the screen instructions.
2. For numeric ID entry, press a key to add a character, and the cursor moves to the right. Up to 20 characters are accepted. If editing an entry, press the left arrow (←) to erase the last character.
3. After data has been entered correctly, press ENTER (↵) as a final step to store the information into memory.

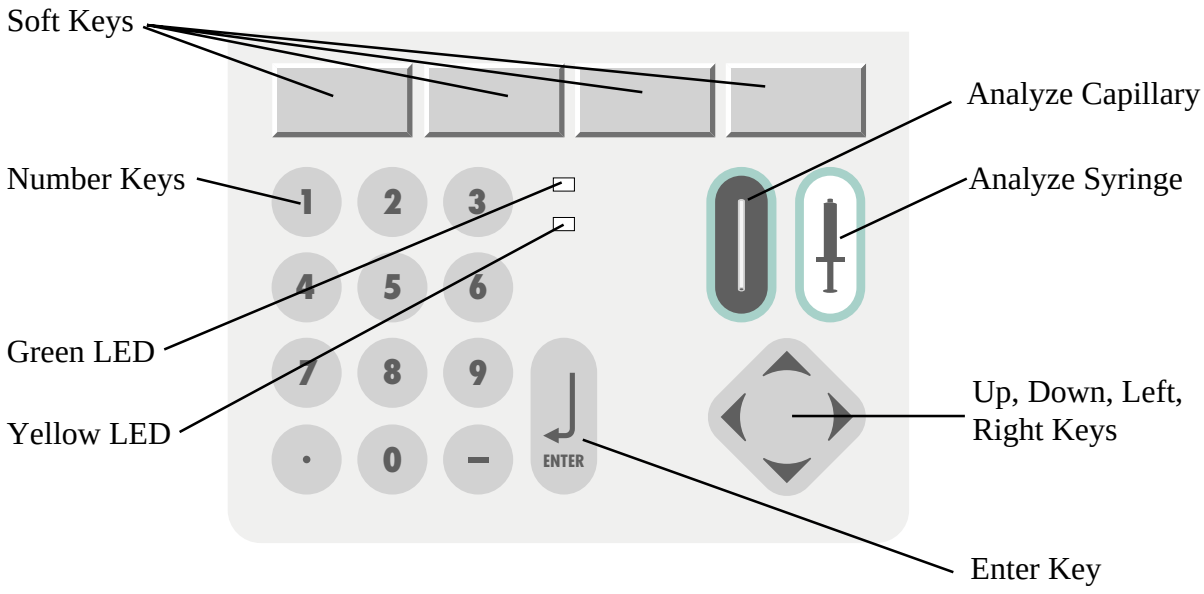


Figure 2-1. Stat Profile pHOx Keypad

2.4 Overview of the Displays (User Interface)

The format that allows the operator to change displays, enter data, and perform functions is generally referred to as the user interface (controlled by software).

Here are some general rules for the user interface:

- To perform any operation, use the screen instructions to guide you.
- To go back to the Ready screen or the menu for a selected section (i.e., QC, Setup, etc.), press Home.
- To move back to the previous display, press Previous Page (soft key), if applicable.
- Press Cancel (soft key) to terminate the current operation or sequence or to return to previous display.
- Press Exit (soft key) to return to the previous display.
- Analyzing a sample and performing calculations take precedence over the user interface. Therefore, you are temporarily locked out of accessing displays that can interfere with an ongoing sequence or operation.
- A status message indicates an error condition.

2.5 Adapting the Program to Your Clinical Requirements with the Setup Menu

Use the Setup Menu to adapt the analyzer to your requirements.

2.6 Setup Options

The Setup Menu has the following setup options:

- **Results Configuration Menu**
  - Reference and Alert Limits Setup
    pH, PCO_2, PO_2, SO_2%, Hct, Hb
  - Electrode Offsets Setup
    pH, PCO_2, PO_2, SO_2%, Hct, Hb
  - Results Units Setup
    Temperature: °C or °F
    Blood Gas: mmHg or kPa
    pH/H^+: pH or H^+
    Hb: g/dL or mmol/L or g/L
  - Results Suppression: Suppress or not suppress
  - Remote Review: ON or OFF
  - Patient Name: ON or OFF
  - Mandatory Patient ID: ON or OFF
- **Operation Configuration Menu**
  - Analysis Configuration
    Analysis Transmit Mode Manual/Auto
    Transmit Diagnostic Data Off/ON
    Analysis Print Mode Manual/Auto
    Print Diagnostic Data OFF/ON
    CO-Ox Data Merge Accession nbr/Patient ID
    Set Analyzer ID Number:
  - Calibration Configuration
    Set 1 Point Calibration Frequency 30, 45 min.
    Set 2 Point Calibration Frequency 2, 4, 6 hr.
    Transmit Diagnostic Data OFF/ON
    Print Diagnostic Data OFF/ON
    Transmit Drift Data OFF/ON
    Print Drift Data OFF/ON
  - System Configuration
    Set Date Format DD/MM/YY,MM/DD/YY,YY/MM/DD
    Set Time Mode 24/12 hr. Mode
    Date and Time Set
    Measured Barometric Pressure 760 mmHg
    Corrected Barometric Pressure 0.0 mmHg
    Set Default Hb Used in Calculations: 14.3 g/dL
    Set Tone Frequency (100-500Hz): 3500 Hz
  - Analysis Mode: A or B
  - Hb Type: Measured or Calculated
  - STAT Mode: ON or OFF

- **Communications Menu**
  - Baud (4800, 9600, 19200)
  - Data Bits (7, 8)
  - Stop (1,2)
  - Parity (None, Even, Odd)
  - External Keyboard: Yes or No
  - Co-oximeter attached: Yes or No
- **Printer** Installed or Not Installed
- **Passwords:** System or Operator
- **Operator Passwords:** ON or OFF
- **Language:** English, Chinese, French, German, Italian, Japanese, and Spanish

2.6.1 Password

The first option you should call up is Set Password: either System or Operator.
The System Password, which safeguards the setup parameters, is required to enter the Setup Menu. Set up System Passwords as follows:

1. Press Menu on the Ready screen to display the Operational Menu screen.
2. Press Setup to display the Setup Menu screen.
3. A pop-up Password screen appears. Enter the default password, 0. This is the password until one is officially entered.
4. Scroll down with the arrow keys to the Password option and press Enter. A pop-up screen appears: select System Password.
5 Key in a password number between 1 and 9999 (up to 4 numeric characters) then press ENTER.
6. Proceed to the next setup option or return to the Operational Menu.

The Operator Passwords allows you the ability to enable and to enter 200 unique passwords with privilege levels. When enabled, password entry will be required whenever any of the home screen soft keys, syringe key, or capillary key are pressed. Entry into any one of the protected areas depends on the privilege level assigned to the operator of the analyzer.
There are 3 privilege levels: Privilege Level 1 is the most privileged operator and Privilege level 3 is the default level.

- Privilege Level 1 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 1 operators do not require PDM review and may override this feature. Level 1 operators can override QC lockout.
- Privilege Level 2 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 2 operators will require PDM review, but may override this feature. Level 2 operators cannot override QC lockout.
- Privilege Level 3 operators have access to analysis only. Level 3 operators will require PDM review before the results are released. Level 3 operators cannot override QC lockout.

Set up Operator Passwords as follows:

1. Press Menu on the Ready screen to display the Operational Menu screen.
2. Press Setup to display the Setup Menu screen.
3. A pop-up Password screen appears. Enter the default password, 0. This is the password until one is officially entered.
3. Scroll down with the arrow keys to the Password option and press Enter. A pop-up screen appears: select Operator Password.
4. Key in a password number, up to 4 numeric characters, and press ENTER.
5. To enable Operator Passwords, scroll down to Operator Passwords then press the Enter key: Off will turn to On.
6. Proceed to the next setup option or return to the Operational Menu.

2.6.2 Results Configuration Menu

The Results Configuration Menu screen allows you to set reference and alert limits (Low and High) for all analytes; to adjust electrode offsets for slope and intercept for all analytes; to select units for temperature, pH, blood gas, and hemoglobin; to turn Remote Review On or Off (operator Password is enabled when On); Mandatory Patient ID (On or Off); Patient Name (On or Off); Global Suppression (Test Results).

2.6.2.1 Remote Review

The operator passwords are enabled whenever Remote Review is enabled. To enable Remote Review (password required), go to the Results Configuration screen, select Remote Review, then press the Enter key to enable (On) - disable is Off.

Features of Remote Review are as follows:

- **Send Results Data to PDM for Review:** When all results and calculated parameters are available, the pHOx Analyzer transmits all this data to the PDM. The analysis cycle is suspended indefinitely until the PDM returns record or the review is bypassed or cancelled.
- **Suppress Results Data:** The PDM will return a reviewed data record to the pHOx Analyzer. The analyzer will suppress test results based on the information received from PDM.
- **Bypass Review:** A pHOx operator with password level 1 or level 2 can bypass a remote review session. When the session is bypassed, the results are saved, displayed, and printed (if automatic printing is on). A reviewed data record sent by PDM is ignored if the review session is bypassed.

- **Cancel Review:** A pHOx operator can cancel a remote review session. When the session is cancelled, the results are saved, but the results will not be displayed or printed. A reviewed data record sent by PDM is ignored if the review session is cancelled.
- **Review Patient Name:** PDM can return a patient name with the suppressed test results. The patient name will be displayed and printed with the result data if the patient name entry feature is ON.
- **Review Accession Number:** PDM can return an accession number with the suppressed test results. The accession number will overwrite the existing accession number. The accession number will be displayed and printed with the result data.

2.6.2.2 Results Suppression

In the Results Configuration screen, test results can be suppressed: will not be displayed, printed, or transmitted. The suppressed results will only affect analysis results: it will still calibrate.

Measured tests that depend on the results from a suppressed test will not be displayed. A dependency error is displayed.

Calculated parameters that depend on suppressed results are not calculated.

Suppress results as follows:

1. In the Results Configuration screen, scroll down to Results Suppression.
2. Press the Enter key to get a pop-up screen of the tests.
3. Scroll to the test that you want to suppress then press the Enter key.
4. Scroll to the next test or exit from screen.
5. On the Home screen, the suppressed test will have a strike through the test; no results will be reported on this test.

2.6.2.3 Mandatory Patient ID

In the Results Configuration screen, the Mandatory Patient ID is enabled or disabled. If enabled, the Sample Information screen will prompt for Patient ID before the sample analysis can continue.

A patient ID can be sent from PDM as part of a remote review session.

A patient ID can also be received from a bar code device or external keyboard through the bar code port.

2.6.3 Operation Configuration Menu

The Operation Configuration Menu screen allows you to setup the analysis output options, to configure calibration frequency, and to set date, time, barometric pressure, analyzer ID number, and to change the analysis mode (A or B); to select Hb Measured or Calculated; to select STAT Mode.

2.6.4 Communications

The Communication screen allows you to setup the communication ports: Baud, Stop, Data, and Parity. Also, the External Keyboard and CO-Oximeter attached (Yes or No) is selected here.

2.7 QC Setup

To access the QC Setup screen, press QC (soft key) on the Ready screen. Then use the down arrow key to select QC Setup and press the ENTER key to display the QC Setup screen.
For External Controls, enter the Lot Number, the Expiration Date, the Daily Analysis Times (up to 3 times per control per day), and the Ranges of each control.
For Internal Controls, the Lot Number, the Expiration Date, and the Control Ranges are automatically read from the control pack when the QC Auto Cartridge is installed. The Daily Analysis Times (up to 3 times per control per day) must be manually entered.

2.7.1 QC Lockout

QC Lockout can be enabled (ON) in one of 2 modes or disabled (OFF) from the QC Setup screen (a password protected screen). When QC Lockout is selected from this screen, a pop-up screen appears. Lockout OFF, Mode A, and Mode B are the choices. When QC Lockout is ON (Mode A or Mode B) and QC is due, all test that are scheduled for QC will be lock out. A QC analysis must be done for a locked out test before an analysis can be performed.

Channel Lockout
A channel will be locked out when it does not pass a QC level. The channel appears with a strike-through it. This channel will not report results unless a password overrides it. When all channels become locked out, the analyzer displays the Not Ready screen.

> ***NOTE:*** *If the QC Lockout feature is OFF, the analyzer will internally keep track (Mode A) of the channels that would be locked out if the QC Lockout feature was ON. If the QC Lockout feature is now turned ON, all those channels will now become locked out.*

Level Lockout
QC level lockout is enforced for both Mode A and Mode B. If a QC level is not run and QC Lockout is enabled, all channels in that QC level will become locked out. These channels remain locked out until the QC analysis cycle of that level is run. A message is displayed on the Ready/Not Ready screen that a QC analysis is due for a particular level.

> ***NOTE:*** *If the QC Lockout feature is OFF, the analyzer will internally keep track of all channels in this level that would be locked out if the QC Lockout feature was ON. If the QC Lockout feature is now turned ON, all those channels will now become locked out.*

QC Lockout is activated by selecting either Mode A or Mode B.
Mode A QC lockout locks or unlocks channels based on the last QC level run. A lockout channel is displayed with a strike-through the channel name. Results for a locked out channel are not calculated. If more than one QC level is run for the QC cycle, only the last QC level that a channel is in determines whether the channel will be locked or unlocked. If 3 levels were run and the channel passed the first 2 levels but failed the last, the channel will be locked out. To be unlocked, this channel must pass that last level: passing the first 2 does not count. If the reverse happened and the channel failed the first 2 levels but passed only the last level, the channel will not be locked out.

Mode B QC lockout locks or unlocks channels based on the last QC run for all levels. A lockout channel is displayed with a strike-through the channel name. Results for a locked out channel are not calculated. If a channel fails any level run in a QC cycle, the channel will be locked. To be unlocked, the channel must pass all levels that it failed.

QC Lockout OFF
When the QC lockout mode is set to OFF, the analyzer internally tracks the lockout state for each channel. The tracking uses the Mode A lockout. If QC lockout is enabled by selecting either Mode A or Mode B, any number of the tracked channel can now become locked out.

QC Lockout is password protected, and a password override (Level 1 operators only) is provided with a pop-up screen. Analysis can be initiated for all channels in a lockout state, but results will be displayed with the message "Scheduled QC Not Run" and printed with this error message.
For Automatic QC mode to perform, turn Automatic QC Analysis ON in the Quality Control screen.
Messages displayed on the Ready/Not Ready screen detail the reason for the QC lockout. These message are only displayed if QC lockout is enabled (Mode A or Mode B). The following are the messages and their meanings.

Level Lockout Ready/Not Ready Screen Messages

Internal L(n) Not Run — Internal L(n) missed a scheduled QC cycle. All channels are locked out for that level. Results for the locked out channels will not be reported. Internal QC level (n) must be run to unlock the channels.

External L(n) Not Run — External L(n) missed a scheduled QC cycle. All channels are locked out for that level. Results for the locked out channels will not be reported. External QC level (n) must be run to unlock the channels.

Mode A Ready/Not Ready Screen Messages

QC Lockout — All channels are locked out. Analysis cannot be run without a password override. Any QC level that is run will unlock the channels.

Mode B Ready/Not Ready Screen Messages

QC Lockout Internal L(n) — Internal L(n) has channels that are locked out. Results for locked out channels will not be reported. Internal QC level (n) must be run to unlock the channels.

QC Lockout External L(n) — External L(n) has channels that are locked out. Results for locked out channels will not be reported. External QC level (n) must be run to unlock the channels.

2.8 Remote Control

Remote control is enabled on the PDM side. See the PDM Manual for information. The analyzer's system ready status information is sent to the PDM upon each change of status: barometer, temperature, reagent pack, control pack, minimum calibration, QC test lockout, QC level lockout, and standby mode state.

The system test status information is sent to the PDM after calibration and QC are completed. This test status information includes the calibration status and QC lockout status of each test and the performance status of glucose.

Remote control from the PDM can do the following:

- Initiate a 2-point calibration sequence
- Run an internal QC (any level)
- Turn global suppression on or off
- Enter or delete passwords
- Maintain a maintenance activity record that is sent to the PDM at the completion of the maintenance. The maintenance status information includes an operator ID, an activity ID, and the date and time of the maintenance.

3 Operation

The Stat Profile pHOx Analyzer is pictured below with its components.

Figure 3.1 Nova Stat Profile pHOx Components

1. Display
2. Keypad
3. Printer
4. Sampler
5. Door/Front Panel

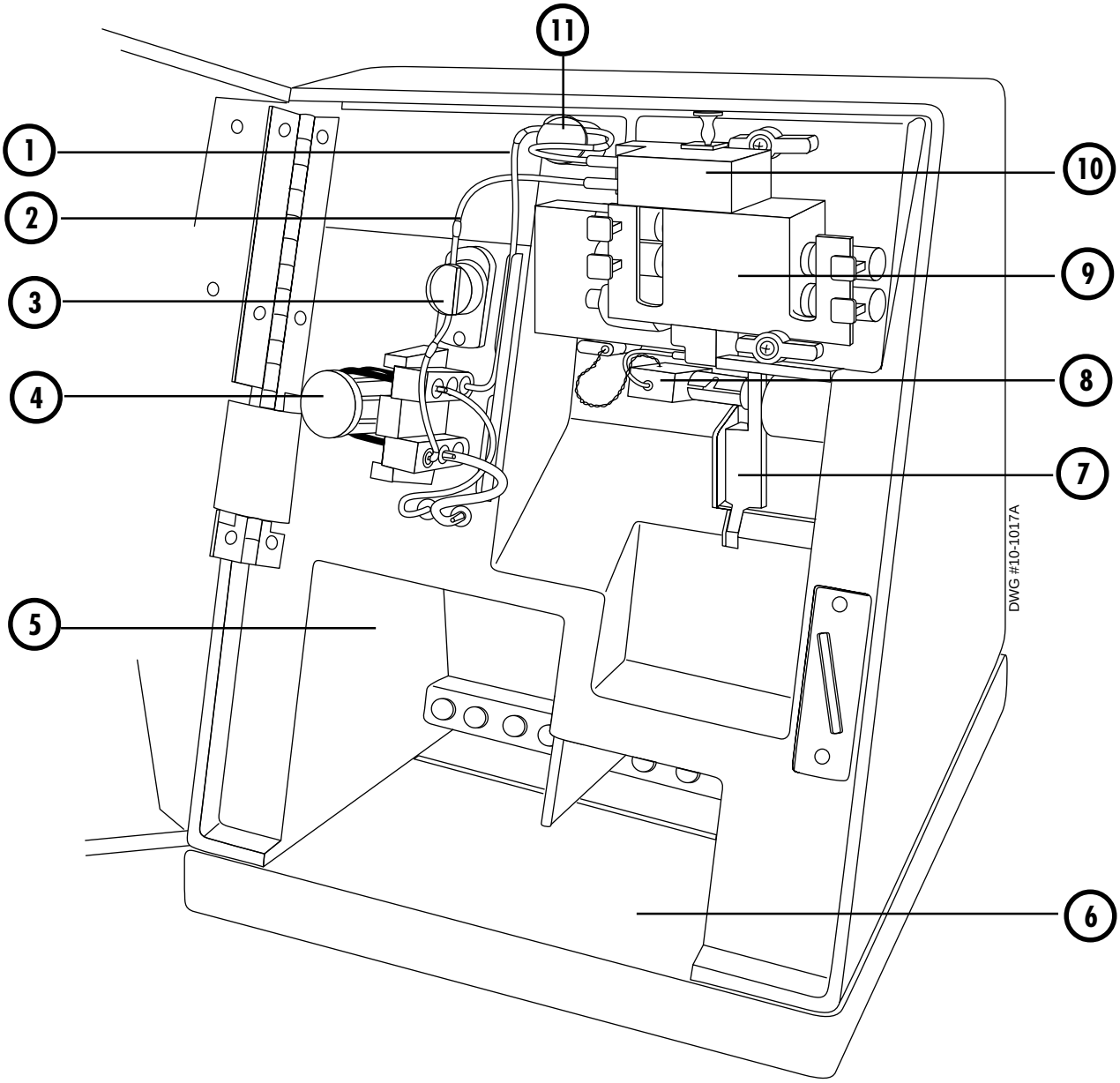


Figure 3.2 Analytical Compartment

1. Waste Line
2. Reference Line
3. Pinch Valve (Reference)
4. Pump and Pump Tubing
5. Reagent Pack Opening
6. Control Pack Opening
7. Sampler
8. Air Detector
9. Sensor Module With Sensors
10. Reference Electrode
11. Pinch Valve (Waste)

3.1 Display and Door

The display is a liquid crystal display (LCD). To adjust the display intensity, use the right (darker) or left (lighter) arrow key while displaying the Ready or Not Ready screen. Prompts, menus, status information, error messages, patient results, etc. are displayed on the screen. The default language is English. (Other languages can be selected through the setup menu.)
The door may be opened to access the analytical compartment of the system. There is an inside latch that is easily released when you pull at the bottom right side of the door.

3.2 Keypad

The primary input device is the keypad. It has the digits (0 thru 9), a decimal point, a dash, an ENTER key, arrow keys (up, down, left, and right), and analyze keys (syringe and capillary icons). There are also 4 Soft Keys whose function is determined by the legend displayed just above it on the LCD display: Print, Exit, Cancel, Menu, etc.

3.3 Printer (Optional)

The internal printer (optional) will be able to print patient results, list the analyzer's setup information, error log, etc.

3.4 Sampler

The sampler allows for the aspiration of the sample. The sampler has 2 sampling positions: horizontal for the aspiration of a sample from a capillary tube and inclined for the aspiration of the sample from a syringe. No special adapters are required to aspirate a sample from a capillary tube. The capillary or syringe positions are selected by pressing the Black Capillary key or the White Syringe key.

3.5 Sensor Module

The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance electrode and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference electrode at the top of the sensor module, 3 sensors on the left side, 2 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 6 sensors: Reference electrode, Na^+, PCO_2, SO_2 (optic), pH, and PO_2. A window in the door allows flow path visibility and is augmented by a backlight.

3.6 Sensors

The Sensors housed in the sensor module are the core of the Stat Profile pHOx Analyzer. The methodology used by each sensor are

Electrode	Methodology
Na^+	Sodium ion-selective electrode
pH	Hydrogen ion-selective glass electrode
PCO_2	Severinghaus-type electrode
PO_2	Polarographic Clark-type electrode
Hct	Impedance electrode
Hb	Impedance electrode/photometry
SO_2	Reflectance photometry (fiber optics)

The sensors clip into the sensor module, and electrical contact is automatically made.

3.7 Reference Electrode

The Reference Electrode is mounted above the sensor module. It is a solid-state Ag/AgCl electrode and provides the reference voltage for comparison to sample voltages. The exit port of the flow path is located on this electrode.

3.8 Barometric Pressure Module

The Barometric Pressure Module, located on a printed circuit board, continuously monitors the barometric pressure. This barometer can be calibrated against an external barometer, if desired, through the software.

3.9 Pinch Valves

There are 2 pinch valves: one is used to control the flow of the reference fluid and the other one is used to control the flow of fluids through the sensor module.

3.10 Peristaltic Pump

The pump is a 6-roller peristaltic pump driven by a stepper motor.

3.11 Reagent Pack

The reagent pack contains 6 flexible bags in a cardboard carton. One of these is a waste bag to collect the used reagents, controls, and samples. The other 5 bags contain standard reagents: A, B, C, D, and R. Each bag includes a fitment with a septa.
The exposed bag fitments are arranged in a line along the rear of the pack. The septa are pierced during insertion of the pack. The lot number and expiration date are printed on the front of the pack.
The Reagent Management System (RMS) of the reagent pack automatically enters the calibration values, the lot number, the fluid volumes, and the expiration date to the analyzer's computer after insertion of the reagent pack.

3.12 Auto-Cartridge QC

Nova Biomedical's Auto-Cartridge QC is a total automated control system contained within a single on-board reagent cartridge. This system allows any level of quality control to be run at any time: either on a programmed schedule or on demand. The Auto-Cartridge QC system reduces costs by eliminating the time and labor required to manually perform quality control.

Each Nova Auto-Cartridge contains 3 levels of blood gas controls, 2 levels of hematocrit, SO_2%, and hemoglobin controls, plus software that automates running controls and storing quality control data. When the cartridge is installed, all quality control target ranges, lot code, and expiration date information is automatically downloaded to the analyzer. The user then programs the pHOx Analyzer to automatically analyze up to 3 quality control levels, 3 times per day (a total of 9 analyses per day). If any analyte is outside the target range, it is automatically reanalyzed. If a control value remains out of range, the user is notified.

All quality control data is automatically stored. Daily and cumulative statistical reports and Levey-Jennings graphs can be printed at any time. This automation assures that quality control is always performed accurately and on schedule, thereby guaranteeing regulatory compliance.-

3.13 Movement Of Fluids

To begin an analysis, press the Capillary or Syringe key to move the sampler to either the capillary or syringe position. Present the sample to the probe and press either Aspirate Normal or Aspirate Micro (soft keys). The Aspirate Normal soft key allows for the aspiration of 70 µL of sample, and the Aspirate Micro soft key allows for the aspiration of 45 µL of sample. The sample is aspirated by the peristaltic pump until the leading edge is detected by either the 45 µL or 70 µL air detector. After the aspiration is completed, there is an audible beep and a pop-up display that prompts you to press Analyze after removing the syringe or capillary. The sample is advanced until the leading edge is properly located in front of the electrodes. Once all measurements have been completed, the sample is pumped to the waste and the flow path is washed.

3.14 Operational Overview

The Stat Profile pHOx Analyzer is a stand-alone, microprocessor-based instrument for analyzing blood samples. The analyzer measures pH, PCO_2, PO_2, SO_2%, Hct, and Hb in heparinized blood. The analyzer additionally calculates the parameters listed in Section 1.2. The software allows the control of the following functions:

- Calibration
- Sample analysis
- Quality Control
- Diagnostic and maintenance functions
- System configurations
- Communication interface with external devices
- Storage and retrieval of patient records

After the analyzer is set up and calibrated, it is ready to begin analyzing samples. Samples can be aspirated from syringes, capillaries, open tubes, small sample cups, or ampules. After sample acceptance, patient data can be entered. A limited number of patient records (18) is stored in a "circular" buffer. Once the buffer is full, each new saved record overwrites the oldest record.

3.15 Ready to Analyze

When the Ready to Analyze screen is displayed, the analyzer is ready to run samples.

The following information is displayed on the screen:

- All calibrated analytes - Uncalibrated analytes are X'd out.
- Next QC time (if selected in Setup)
- Next Calibration time
- Amount remaining for reagents (A bar graph is displayed for fluid volumes greater than 10% of the original volume.)
- Soft keys
    - Results - Patient
    - QC - Run Quality Control Samples
    - Calibrate
    - Menu (Operational)

3.16 Calibrating the Analyzer

The analyzer uses a 2-point calibration to measure pH, PCO_2, PO_2, Hct, Na^+ electrode slopes and to verify electrode performance. This 2-point calibration occurs automatically at regular intervals, or, if desired, calibration can be manually initiated. The options are listed in the Calibration screen. If an electrode fails to calibrate for any reason, an appropriate error code is generated. An operator can cancel a calibration in progress from the keypad to run a stat analysis. If this is done, the previous calibration slopes are used for the analysis calculations.

3.16.1 Two-Point Calibration (Automatic and Manual)

The analyzer performs an automatic 2-point calibration at 2, 4 or 6 hour intervals (as selected in Setup). These Auto-Cal intervals can be extended as follows:

Auto-Cal Extension: System Busy when Auto-Cal scheduled to run

If the system is busy when an Auto-Cal is scheduled to run, the request is held in a queue until the current sequence is completed. The system presents the operator with a pop-up that allows the delay of a 2-point calibration sequence for an additional 10 minutes. The 2-point calibration sequence may be delayed indefinitely.

3.16.2 Manual Calibration

Manual calibrations may be initiated to calibrate any uncalibrated electrodes or calibrate the system after maintenance. Press the soft key for Calibrate on the Home screen. The 2-point Calibration screen is displayed with options for calibration. Use the arrow keys to go to the desired option. Then press ENTER.

3.16.3 SO_2/Hb Calibration

SO_2 and Hb must be manually calibrated with 2 external calibrators. To calibrate SO_2 and Hb, press Calibrate on the Home screen. Then go to option 2 and press Enter. Follow the directions on the screen. You will be asked to enter the assay values for each level of calibrator. These 2 values can be verified on the SO_2 Sensor Subsystem screen.

3.16.4 One-Point Calibration

All analytes are checked for calibration every 30 or 45 minutes if analysis Mode A was selected in the setup options. This check is done by exposing the electrodes to a known standard and comparing the new value to the value obtained during the 2-point calibration. A calibration drift error is generated if the difference exceeds the internally set limits. The flagged sensor will revert to an uncalibrated state.

> ***NOTE:*** *If Mode B is selected, a 1-point calibration does not take place every 30 or 45 minutes, instead the 1-point calibration is automatically performed with each sample analysis..*

3.17 Quality Control

The Quality Control screen is accessed from the Home screen by pressing QC (soft key). Times for running QC can be set through the QC Setup. This menu also allows access to reports and manipulation of daily, monthly, cumulative data, and Levy Jennings graphs.

Definitions:
Daily Statistics - All QC samples stored since the last Move Daily Data to Month-to-Date was performed. Daily data accumulation begins at midnight of the current day.
Monthly Statistics - Cumulative statistics for the last 32 days. Monthly statistics are simply cumulative statistics.
Cumulative Statistics - A running accumulation of mean, SD (standard deviation), and CV% (coefficient of variance in percent) for all stored QC samples. Although these statistics are based on the total number of samples, the n on the screen and on the printout indicates the number of days. The Cumulative Statistics cannot be reset except by changing to a control with a new lot number.

> ***NOTE:*** *When the SD approaches zero and is smaller than the display range of that analyte, the SD result for that analyte is not displayed (blank screen).*

When a new Auto-Cartridge QC with a new lot number is installed, the data from the previous lot number is erased from the memory of the analyzer. Thus, you are unable to run lots in parallel to validate the new lot to the old by alternating packs on the same unit.
Nova Recommendation: All Nova controls ship with a product insert sheet. This product insert sheet contains the target value ranges for each level of QC contained in the pack. Nova's recommendation for conversion to a new lot number is to use the product insert sheet range levels for the first 30 days or until sufficient data is collected to establish the new target values. After sufficient data is collected, the established values and ranges can be entered into the analyzer.
Alternate Method: If this method is inadequate, Nova recommends the use of the external controls run in parallel and overlapping with the on-board product change over. This method offers continuity in monitoring performance during the change over period, but it does add cost. The external QC monitoring can be done using the QC program on the analyzer.

3.17.1 Running QC Samples

From the Home screen, press QC (soft key) to display the Quality Control (QC) screen. Follow the instructions on the screen.

NOTE: *If the mandatory QC mode is selected (i.e., QC times have been entered) and you choose to delay or not run the QC, a message is displayed indicating that QC was not run. If the QC lockout mode is selected and a scheduled QC is not allowed to run, the analyzer becomes Not Ready.*

If you power up without QC scheduled and QC Lockout off, the analyzer will boot up in control.

NOTE: *To use the Auto QC mode, set the times for the 3 control levels in the Setup QC Levels screens, then turn Automatic QC Analysis ON in the Quality Control (QC) screen.*

3.17.2 Running Linearity Solutions/Proficiency Samples

From the Home screen, press QC (soft key) to display the Quality Control (QC) screen. Then select Proficiency. Follow the instructions on the screen.

NOTE: *When a sample is run in this mode, slopes and offsets do not apply.*

3.18 Analyzing Samples

Samples can be analyzed from capillaries of various sizes and glass or plastic syringes from 1 cc to 10 cc. Samples are aspirated from a horizontal position for capillary tubes through a built-in adapter or at a 30° angle from the horizontal for syringes and ampule control samples.

1. Once the Capillary or Syringe button is pressed, the Aspirate screen is displayed.
2. Press one of the soft keys: Aspirate Micro or Aspirate Normal.
3. Then press Aspirate (soft key). The Sample Information screen is displayed.
4. The Sample Information screen is 2 screens. Screen 1 has Accession number, Patient ID number, Patient Temperature, Combine CO-Ox Data (yes/No), Operator ID, and Patient Name.
   Screen 2 has Sample Type (Arterial, etc.), Puncture Site (Radial Artery, Brachial Artery, Femoral Artery, Arterial Catheter, or Unspecified), Ventilator Rate/Min, Tidal Volume, PEEP/CPAP, and Mode of Therapy (Unspecified, CMV, ACV, SMV, PEEP, CPAP, PSV, PCV).
5. Press View Results (soft key) to display the Results - Measure screen. To view all results (measured and calculated), continually press Next Page (soft key).

3.18.1 Analyzing from a Syringe or an Ampule

From the Home screen (Ready for Analysis), press the syringe key (for syringe or ampule samples) to position the probe. To aspirate the sample, press Aspirate Normal (soft key). Follow the directions on the screen.

> ***NOTE:*** *To run in micromode, press Aspirate Micro (soft key). The time is typically longer than normal mode. For other functions, follow the screen instructions.*

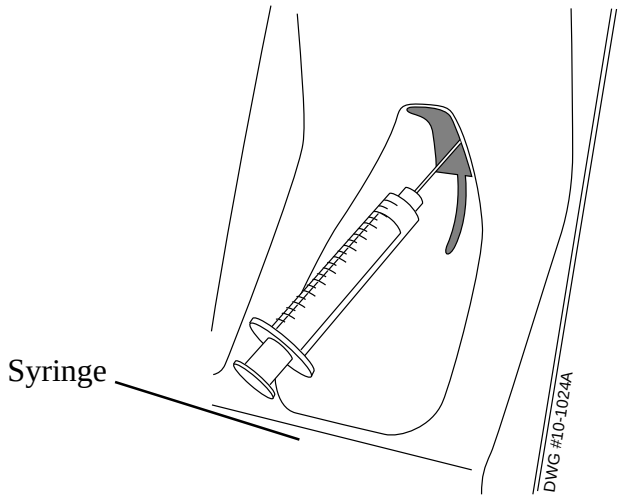


Figure 3.3 Analyzing from a Syringe

3.18.2 Analyzing from a Capillary Tube

From the Home screen (Ready for Analysis), press the Capillary key to position the probe. To aspirate the sample, press Aspirate Normal (soft key). Follow the directions on the screen.

> ***NOTE:*** *To run in micromode, press Aspirate Micro (soft key). The time is typically longer than normal mode. For other functions, follow the screen instructions.*

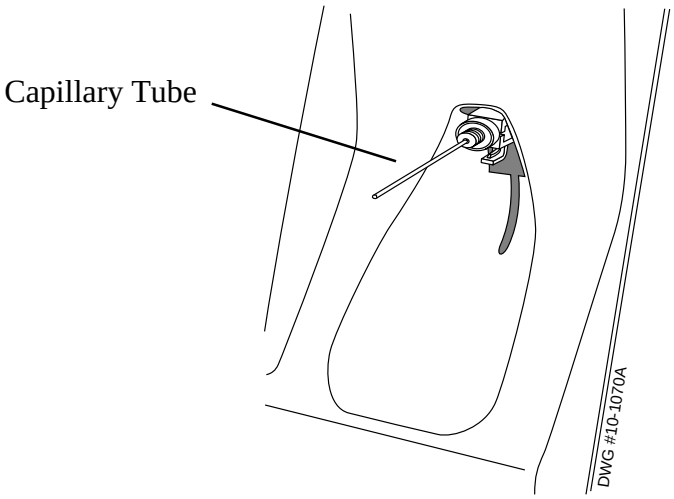


Figure 3.4 Analyzing from a Capillary Tube

3.18.3 Analyzing in AV Shunt Mode

The AV Shunt sample analysis combines both the pHOx and the CO-Oximeter results for 2 sample types: mixed venous and arterial. The mixed venous is analyzed first on the pHOx, then the same sample is analyzed on the CO-Oximeter. Next the arterial is analyzed: first on the pHOx then on the CO-Oximeter. Follow this procedure with the aid of the pHOx screen prompts:

1. From the Home screen (Ready for Analysis), press the Syringe key to position the probe.
2. Press AV Shunt (soft key).
3. Position the mixed venous sample and press Aspirate (soft key).
4. Remove the sample and press Analyze (soft key).
5. Run the same venous mixed sample on the CO-Oximeter.
6. When message, Mixed Venous sample complete, is displayed, analyze the arterial sample. Position arterial sample and press Aspirate (soft key).
7. After aspiration, remove sample and press Analyze (soft key).
8. Run the same arterial sample on the CO-Oximeter.
9. Press Results (soft key) to get all the results including the combined results.

3.18.4 Stat Mode

Stat Mode is turned ON or OFF in the Operation Configuration Menu screen. When Stat Mode is ON, the Sample Information screen is not displayed each time an analysis is initiated.

3.19 Results Recall

Previously analyzed samples can be recalled for viewing only. These records are stored in a circular buffer. When the buffer becomes full (greater than 18 analyses), the oldest record in the buffer is overwritten. The record is automatically saved by the analyzer when the analysis is successfully completed. The results are cataloged by date, time, accession number, and ID number. These results are accessed through the Ready screen.

> ***NOTE:*** *When connected to a computer and you want to retransmit the results, follow the results recall steps, then when the results are on the screen press the decimal (.) key, then the Print (soft Key). The results should then retransmit.*

> ***NOTE:*** *Proficiency results are not stored.*

1. From the Ready screen, press Results (soft key).
2. Use the arrow keys to select the desired results. (Or press Latest Results (soft key) to view the last sample analyzed.)
3. Press ENTER to view the selected results.
4. Follow directions on the screen.

4 Operating Procedures

The following sections provide detailed information and directions to operate the Stat Profile pHOx Analyzer at peak efficiency. From the Home screen, press Menu (soft key).
From the Operational Menu screen, the following options can be performed:

- Set Sample Number Counter
- Change the Reagent Pack
- Change the Control Pack
- Flowpath/Probe maintenance: change tubing, sensors, purge, etc.
- Flowpath Cleaning
- Sensor Conditioning
- Standby Mode

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, probe, sensor module, etc.) with care. Gloves and protective clothing are recommended.

A **Maintenance Log** that includes performance records and a maintenance checklist is supplied with your instrument. Use this log to record data for long-term performance verification and to document maintenance.

4.1 Sample Number Counter

The screen allows you to check and/or to change the Sample Number Counter, but the Total Samples Accepted number, the Total Internal QC Samples Accepted number, and the Total Samples and Internal QC number are read only.

4.2 Scheduled Maintenance

It is important to perform preventive maintenance as scheduled. The **Maintenance Log** (PN 22362) gives suggested schedules based on sample volume. Space is provided for slopes and control results in the **Maintenance Log.**

4.2.1 Reagent Pack and Control Pack Changing

The reagent pack and/or control pack should be changed when the system indicates the pack is empty. From the Operation Menu screen, select Change Reagent Pack or Change Control Pack and press Enter. **Mix the pack thoroughly by inverting several times.** Then follow the directions on the screen to replace the packs and the capillary adapter.

WARNING: *When the reagent pack or control pack is removed, keep your fingers and hands away from the back of the pack compartment. There are sharp needles that can cause injury, and the waste needle is also a biohazard.*

NOTE: *The reagent or the control pack must be replaced through the Operation Menu screens. If you remove and replace a pack (even if it is the same pack) outside these screens, you will not be able to prime the analyzer, and you will not be able to calibrate or to analyze samples (Reagent Pack) or to analyze internal controls (Control Pack). If you have removed and replaced a pack outside these screens, go to the appropriate screen and press Prime (soft key).*

NOTE: *The capillary adapter comes in the reagent pack box. As you put on the new adapter, make sure the probe goes through the center hole of the adapter.*

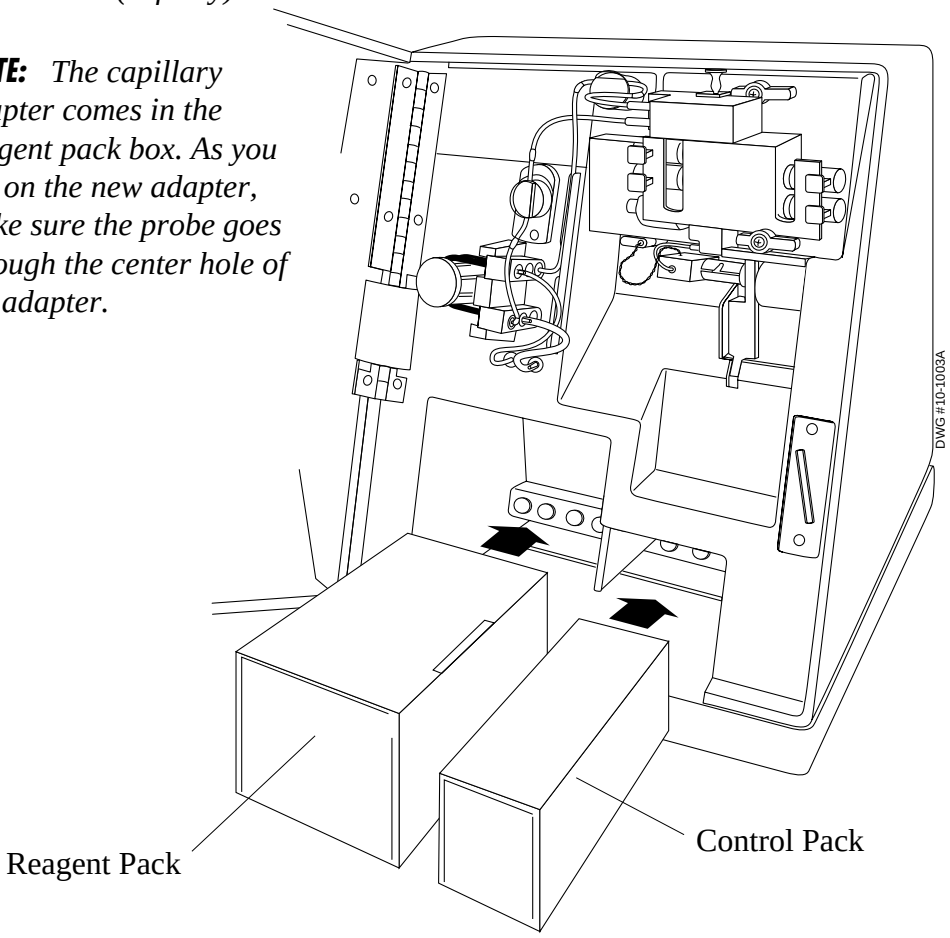


Figure 4.1 Replacing the Reagent Pack and the Control Pack

4.2.2 Flowpath/Probe Maintenance

The Flowpath/Probe Maintenance option removes fluid from the flow path, so that tubing, sensor, or probe changes, or other maintenance can be performed without fluids leaking or pumping into the analyzer. After all replacements are made, press Continue (soft key) to prime the flow path. The analyzer will prime and give you the option to calibrate now or later.

4.2.3 Standby Mode

This option allows you to place the analyzer into a standby mode and allows you to reactivate the analyzer out of the mode at a programmed time and date. The standby mode will use less reagents and controls because the analyzer will not run its automatic calibration cycles. Calibration is lost except for SO_2 and Hb. Standby mode ends after the set time is elapsed; if you turn Standby off; or if you initiate a calibration. The analyzer automatically performs 2 calibrations or a second calibration after Standby mode ends.

The following is the procedure to set the Standby Mode:

1. From the Operational Menu, scroll down to the Standby Mode with the Down Arrow key.
2. Press ENTER (once if OFF or twice if ON).
3. To set the date, press ENTER again - the date becomes blank.
4. Key in the date that you want the analyzer to come out of Standby Mode.
5. Press ENTER to set (DO NOT press OK).
6. Press any Arrow key to change the time. Then press ENTER - the time becomes blank.
7. Key in the time that you want the analyzer to come out of Standby Mode.
8. Press ENTER to set (DO NOT press OK).

9a. Press OK (soft key) to go into Standby Mode. Another pop-up screen appears to verify that you want to go into Standby Mode. Press OK (soft key) again. Standby Mode is now ON.

9b. Press Cancel (soft key) to cancel Standby Mode. The date and time reverts to the previous settings. The Standby Mode is now OFF.

4.2.4 pH and Sodium Sensors Replacement

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door and locate the pH or sodium sensor.
3. Remove the sensor from the sensor module by pinching the front and rear of the sensor clip.
4. Clean the sensor module cuvette with a cotton swab.
5. Insert the new sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
6. Press the Continue key (soft key).
7. A message displays, Priming Flow Path. Please wait until the time bar completes.
8. Recalibrate.

4.2.5 PCO_2 Sensor or Membrane Replacement

The following procedure explains how to replace the PCO_2 sensor and membrane.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door.
3. Locate the PCO_2 sensor.
4. Remove the PCO_2 sensor by pinching the front and rear of the sensor clip and sliding it out of the sensor module. Be careful not to touch the electrical contacts.
5. Unscrew the used membrane cap from the sensor body and discard it.

> ***NOTE:*** *If installing a new sensor, carefully remove the shipping cap before installing a new membrane cap. Do not touch the electrical contacts of the sensor.*

6. Take a new PCO_2 Membrane Cap (PN 25048) that is prefilled with internal filling solution. Hold the shipping plug end of the membrane cap and shake it gently, as if shaking down a thermometer, to ensure that the air bubble is at the threaded end of the membrane cap.

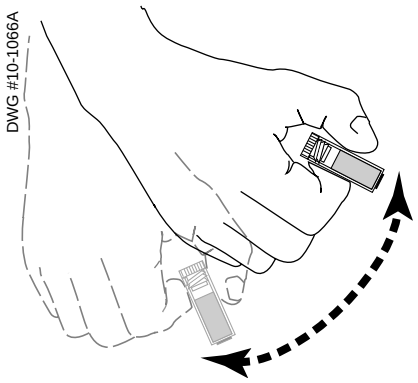


Figure 4.2 Shaking Down Membrane Cap

7. Unscrew the black shipping plug from the cap. Screw the cap onto the sensor. Discard the black shipping plug. Do not tilt the membrane cap when installing onto the sensor; the internal filling solution may drip out.

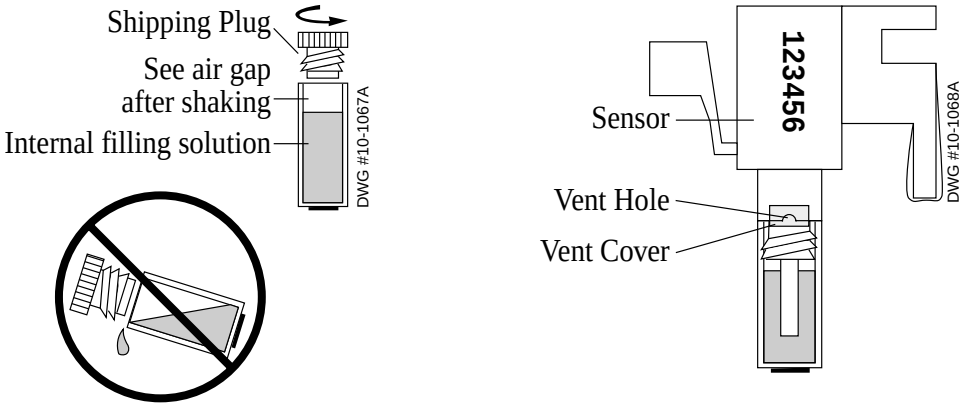
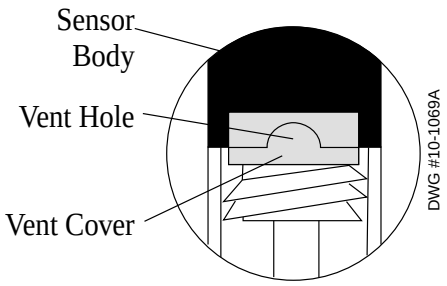


Figure 4.3 The PCO_2 Membrane Cap (With Shipping Plug and Attached to Sensor)

NOTE: *The prefilled PCO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the sensor's performance.*



8. Degas the sensor as follows:
   a. Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
   b. With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.
9. Wipe the sensor body and cap dry. Remove a single vent cover from the blue backing and place over the vent hole (see Figure 4.4). Press firmly to ensure a good seal.

Figure 4.4 Vent Cover on Membrane Cap

10. Clean the sensor module cuvette with a cotton swab.
11. Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
12. Press the Continue key (soft key).
13. A message displays, Priming Flow Path. Please wait until the time bar completes.
14. Condition the sensor module.

NOTE: *All sensors must be in the sensor module during a Sensor Conditioning cycle.*

   a. Fill a 2 mL sample cup 1/2-full of whole blood.
   b. Select Sensor Conditioning from the Operation Menu and press Enter.
   c. Immerse the probe in the sample.
   d. Press Continue to aspirate the sample. Withdraw the cup after the tone.
   e. A message displays, Flow Path conditioning in progress. Please wait until the time bar completes.
15. Return to the Home screen and calibrate the sensor 2 times.
16. If the sensor does not calibrate due to slope errors, remove air bubbles as follows:
   a. Open the door, remove the sensor and shake down the sensor with a wrist-snapping motion to move air bubbles to the back of the sensor.
   b. Reinsert the sensor into the sensor module and close the door.
   c. Recalibrate.

4.2.6 PO_2 Sensor Polishing and Membrane Replacement

The following procedure explains how to polish and to replace the PO_2 sensor and/or to replace the membrane cap.

> ***NOTE:*** *The PO_2 sensor should be polished during routine membrane replacement or during troubleshooting characterized by either slope and/or QC recovery problems.*

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door and locate the PO_2 sensor.
3. Remove the PO_2 Sensor by pinching the front and rear of the sensor clip and sliding it out of the sensor module.
4. Unscrew the used PO_2 cap from the PO_2 body and dispose of it.
5. **If polishing the sensor is unnecessary, go to Step 7 to replace the PO_2 cap.**
6. Polish the sensor as follows:
   a. Take a polishing paper from kit PN 21795 and place a couple of drops of deionized water onto it.
   b. Hold the PO_2 polishing paper so that the tip of your index finger provides light pressure against the back of the paper.
   c. Gently polish the sensor tip on the paper, move the tip in a circular motion for about 10 seconds. Discard the polishing paper.
   d. Wipe the sensor tip with a lint-free tissue soaked in deionized water.

> ***CAUTION:*** *Never polish the sensor tip on a hard surface such as a bench top.*

7. Take a new PO_2 Premembraned Cap (PN 21795) that is prefilled with internal filling solution, and shake it gently to ensure that the solution is away from the threaded end and at the membrane end. Unscrew and discard the shipping plug from the cap.
8. Insert the sensor body straight down (vertical position only to ensure no loss of internal filling solution) into the filled cap and screw the cap onto the sensor body. (See Figure 4.5.)

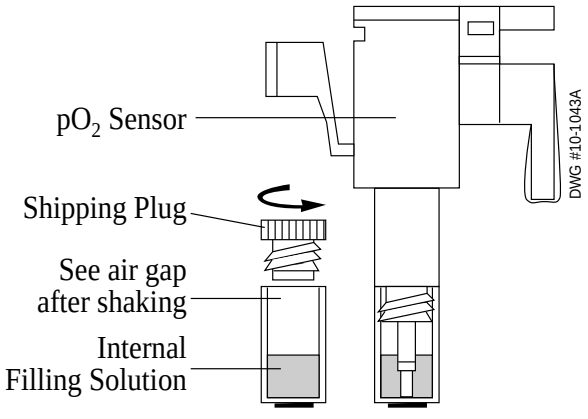


Figure 4.5 Installing the PO_2 Membrane Cap

> ***NOTE:*** *The prefilled PO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the sensor's performance.*

9. Degas the sensor as follows:
    a. Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
    b. With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.
10. Dry the sensor with a lint-free tissue. Take care not to touch the tip.
11. Clean the sensor module cuvette with a cotton swab.
12. Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
13. Close the door and press the Continue key (soft key).
14. A message displays, Priming Flow Path. Please wait until the time bar completes.
15. Condition the sensor module.

    NOTE: *All sensors must be in the sensor module during a Sensor Conditioning cycle.*

    a. Fill a 2 mL sample cup 1/2-full of whole blood.
    b. Select Sensor Conditioning from the Operation Menu and press Enter.
    c. Immerse the probe in the sample.
    d. Press Continue to aspirate the sample. Withdraw the cup after the tone.
    e. A message displays, Flow Path conditioning in progress. Please wait until the time bar completes.
16. Return to the Home screen and calibrate the sensor 2 times.
17. If the sensor does not calibrate due to slope errors, remove air bubbles as follows:
    a. Open the door, remove the sensor and shake down the sensor with a wrist-snapping motion to move air bubbles to the back of the sensor.
    b. Reinsert the sensor into the sensor module and close the door.
    c. Recalibrate.

4.2.7 Reference Electrode Replacement

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door.
3. Disconnect the W and R-lines from the reference electrode.
4. Pull up the retaining screw.

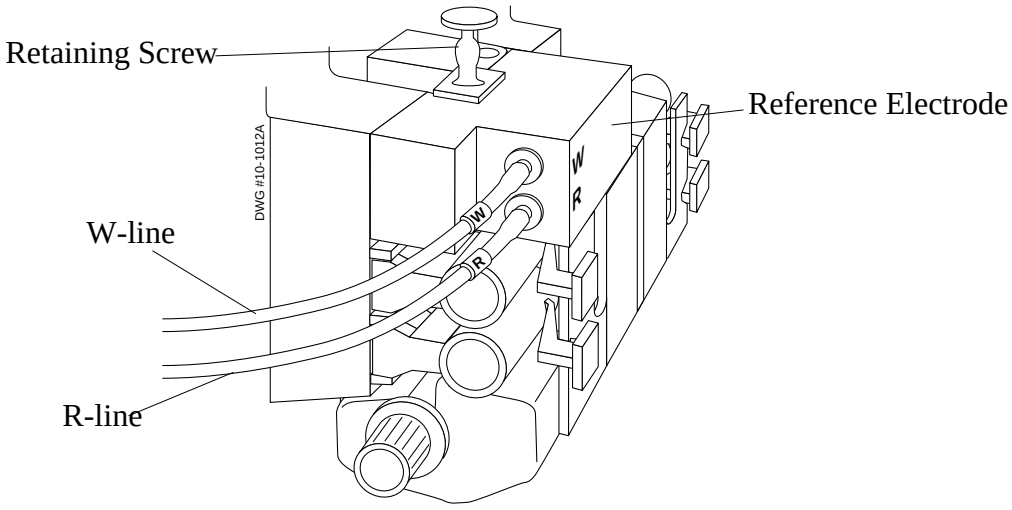


Figure 4.6 Disconnecting the Reference Electrode

5. Lift the used reference electrode up and out of the way of the sensor module.
6. Place the new Reference Electrode (PN 06025) on top of the sensor module, align the electrode sides with the backplate sides. Ensure that the reference electrode connector is seated properly on the sensor module interconnect tubing.

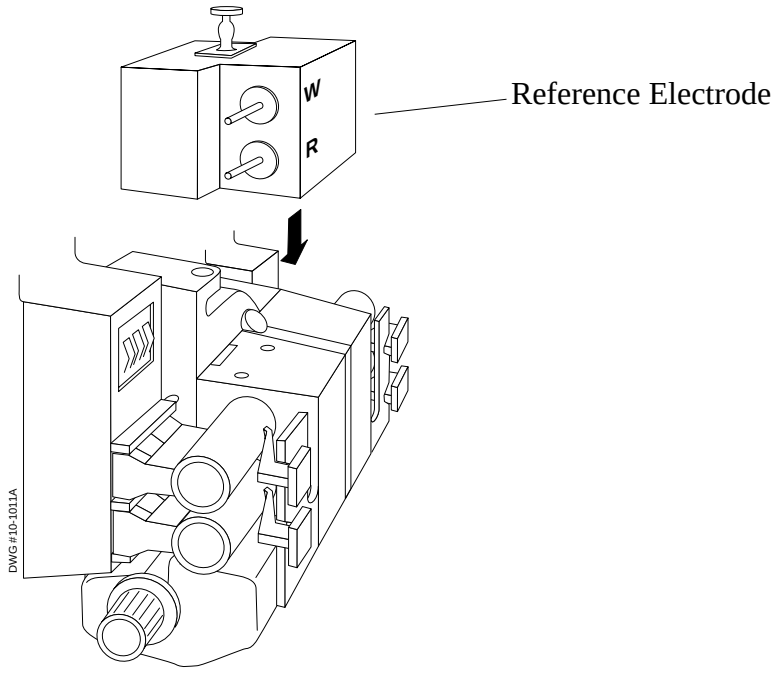


Figure 4.7 Placing New Reference Electrode onto Sensor module

7. Push down on the retaining screw.
8. Attach the W/R-lines to the reference electrode and press Continue (soft key).
9. A message displays, Priming Flow Path. Please wait until the time bar completes.
10. Recalibrate.

4.2.8 SO_2 Sensor Maintenance

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door and locate the SO_2 sensor.
3. To remove the sensor, unscrew the lead screw and pull out.
4. Clean the sensor surface with a lint-free tissue that is soaked with 10% Sodium Hypochlorite Solution (bleach). Rinse with deionized water and blot dry.
5. Clean the sensor module cuvette with a cotton swab.
6. Reinstall the sensor and tighten the lead screw.

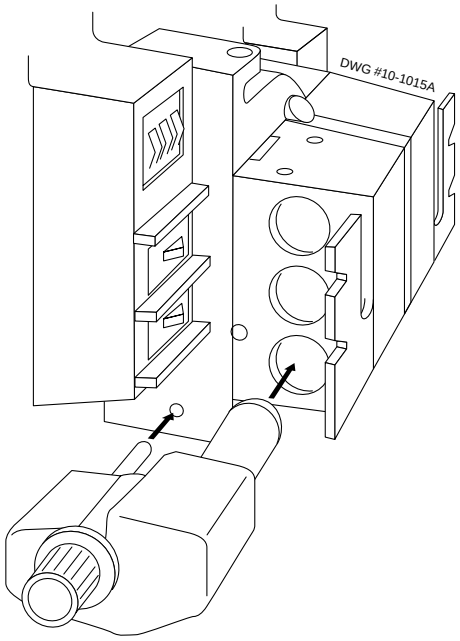


Figure 4.8 Reinstalling the SO2 Sensor

7. Press Continue (soft key) to prime the flow path.
8. A message displays, Priming Flow Path. Please wait until the time bar completes.
9. From the Home screen, press Calibrate (soft key).
10. Follow the instructions on the screen.

4.2.9 Pump Tubing Replacement

The pump tubing should be replaced at intervals prescribed in the maintenance log. Replace the tubing that goes around the pump as follows.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door.
3. Disconnect the R-line and W-line (the ones that go through the pinch valves) from the pump manifold.
4. Disconnect the R and W-pump tubing lines from the labeled outlets that are below the pump manifold.
5. Slide the top and bottom tube manifolds out
6. Discard the used tubing and manifolds.
7. On the new pump tubing, Locate the half circle on one of the manifolds. This is the top manifold.

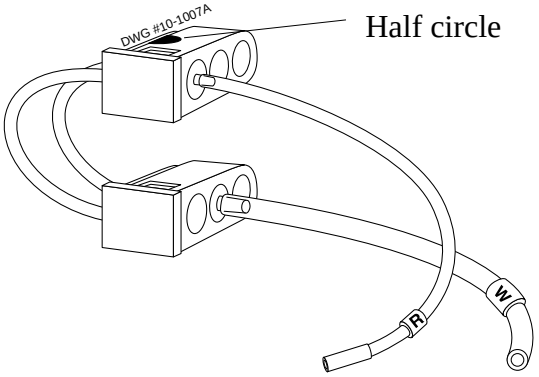


Figure 4.9 Pump Tubing

8. Slide the top pump tubing manifold into its slots. The top manifold's half circle should line up with the half circle on the slot.
9. Stretch the pump tubing around the pump and slide the bottom manifold into its slots.
10. Connect the R-pump tubing line to the R-labelled outlet below the pump manifold (see Figure 4.10).
11. Connect the W-pump tubing line to the W-labelled outlet below the pump manifold (see Figure 4.10).

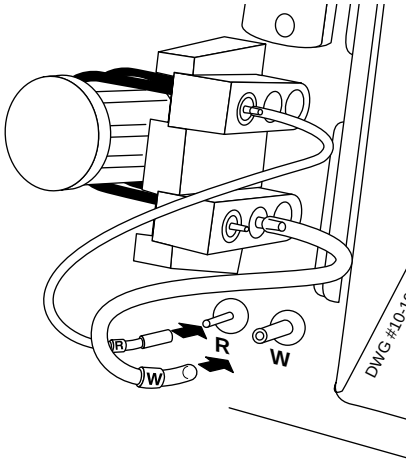


Figure 4.10 Connecting the Pump Tubing W and R-lines

12. Reconnect the R-line and W-line (the ones that go through the pinch valves) to the pump manifold.
13. Close the door and press the Continue key (soft key).
14. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.
15. Recalibrate.

4.2.9.1 Waste Line Replacement

The waste line should be replaced at intervals prescribed in the maintenance log. The W-line connects at the middle of the top pump manifold, travels through the waste pinch valve, and connects to the top W-labelled outlet on the reference electrode. The W-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door.
3. Disconnect the W-line from the pump manifold, pinch valve, and reference electrode. Discard the used tubing.
4. Attach the new W-line starting with the pinch valve. At the pinch valve segment of the W-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the W-labelled outlet of the reference electrode and the middle of the top pump manifold. (See Figure 4.11.)

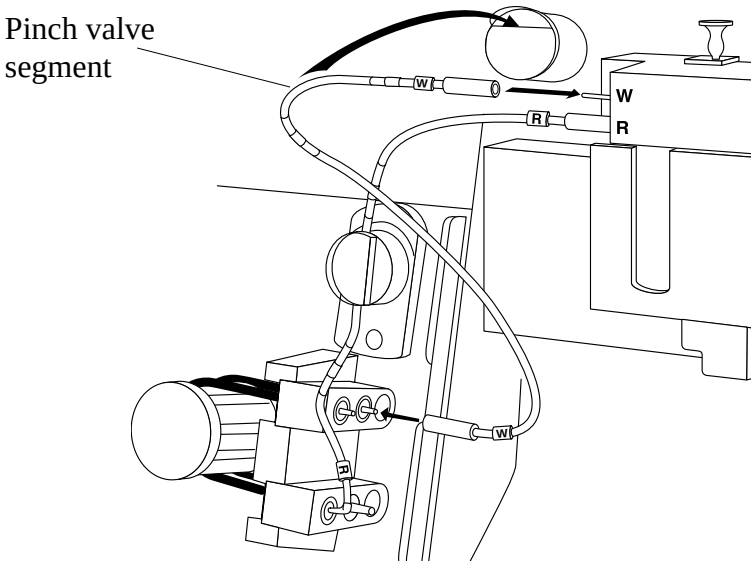


Figure 4.11 Connecting the W-line

6. Close the door and press the Continue key (soft key).
7. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.
8. Recalibrate.

4.2.9.2 Reference Line Replacement

The reference line should be replaced at intervals prescribed in the maintenance log. The R-line connects at the outside of the bottom pump manifold, travels through the reference pinch valve, and connects to the bottom R-labelled outlet on the reference electrode. The R-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door.
3. Disconnect the R-line from the pump manifold, pinch valve, and reference electrode. Discard the used tubing.
4. Attach the new R-line starting with the pinch valve. At the pinch valve segment of the R-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the R-labelled outlet of the reference electrode and the outside of the bottom pump manifold. (See Figure 4.12.)

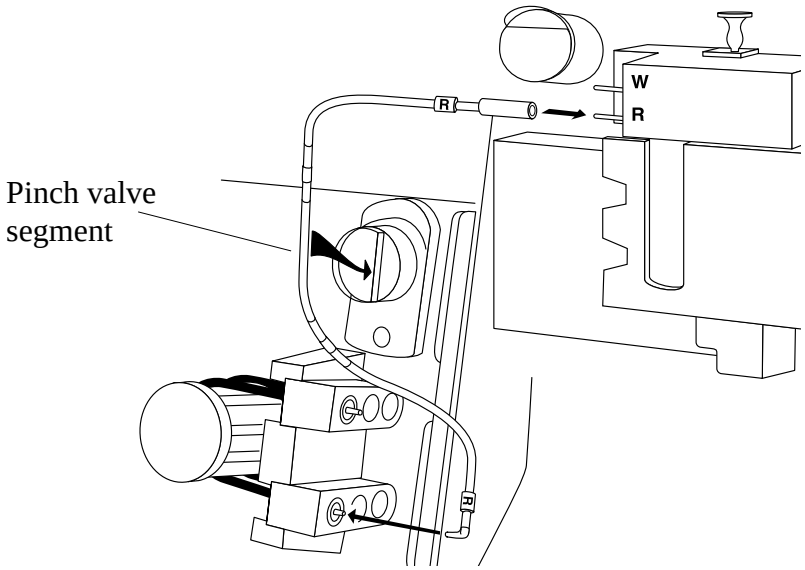


Figure 4.12 Connecting the R-line

6. Close the door and press the Continue key (soft key).
7. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.
8. Recalibrate.

4.2.10 Sensor Module Conditioning

The sensor module is conditioned with whole blood if it is a new sensor module or after cleaning it. The instrument aspirates blood into the sensor module, holds it for 5 minutes, then flushes the module. Condition the module as follows:

1. Fill a 2 mL sample cup 1/2-full with whole blood.
2. From the Operational Menu, select Sensor Conditioning and press Enter.
3. Immerse the probe in blood and press Continue.
4. After the tone, remove the cup from the probe, and press Analyze.
5. The message, Sensor Conditioning in Progress. Please wait for completion, is displayed. To stop the cycle, press Cancel.
6. Recalibrate.

4.2.11 Flowpath Cleaning/Deproteinizing

Nova recommends the use of Deproteinizing Solution (PN 12704) when **routine cleaning** is required. Use, for example, if flow problems persist, if air detectors become uncalibrated, or if PO_2 results are consistently low. To clean the sample preheater, the analyzer aspirates Deproteinizing Solution, a specially formulated solution, into the sample preheater, where the solution dissolves protein buildup. The following are more detailed instructions than displayed on the screen.

> ***NOTE:*** *Terminating a flow path cleaning will trigger a flush sequence before the Ready For Analysis screen is displayed.*

1. From the Operational Menu screen, select Flowpath Cleaning.
2. Wait for the pump to stop. Then remove the sodium sensor and replace it with a blank.
3. Immerse the probe into an ampule of Deproteinizing Solution. Then press continue.
4. After the tone, remove the probe from the ampule. Then press Analyze.
5. Wait for the flow path cleaning cycle to complete.
6. Select Flowpath/Probe Maintenance.
7. Remove the blank and replace it with the sodium sensor.
8. Recalibrate.

4.2.12 Printer Paper Replacement

1. Open the printer cover.
2. Open the printer lever. Gently pull the lever to its opposing position and remove the depleted roll of paper.
3. Remove the paper holder from the used roll of paper and discard the roll.
4. Insert the paper holder into a new roll of paper. The loose end of the paper should feed from the bottom of the roll.
5. Install the roll of paper with holder into the support collars.
6. Push the paper through the back of the roller. Manually move the roller by using the knob next to the platen.

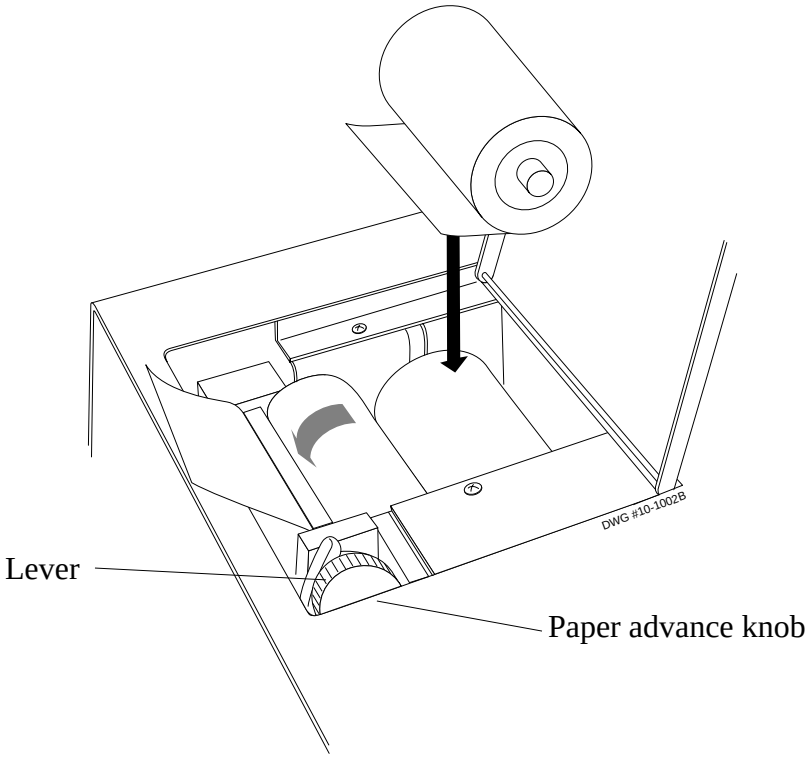


Figure 4.13 Replacing the Printer Paper

7. Center the paper and close the printer lever by pushing the lever back to its original position.
8. Feed paper through cover. Then close the printer cover.

4.2.13 Probe and Air Detector Replacement

If the probe or air detector becomes damaged, replace it. Use the following procedure when to replace the probe or the air detector.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.

   NOTE: *If you are just changing the air detector, skip to Step 4.*

2. Press Move Probe (soft key). Open the door.
3. Remove the capillary adapter from the front of the probe by gently pulling.
4. Disconnect the air detector's sample line from the sensor module.
5. Disconnect the 2-prong cable of the air detector from the analyzer.
6. If changing the probe, push the air detector down and pull the air detector with probe out of the sampler assembly.
   If changing only the air detector, push the air detector down and pull the air detector out. Replace with new air detector and skip to Step 9. DO NOT remove the probe if just the air detector is to be changed.

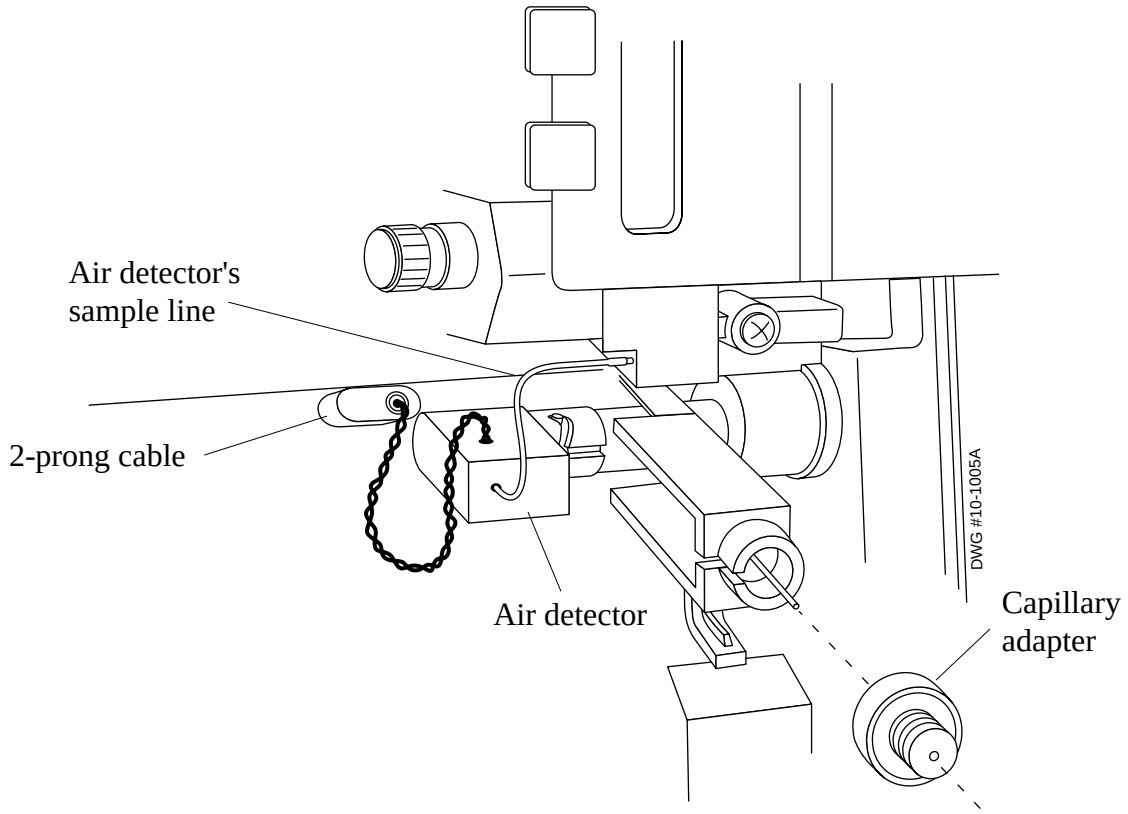


Figure 4.14 Removing Capillary Adapter

7. Discard the used probe.
8. Place a new probe into the air detector and slide both into the sampler assembly.

9. Push the air detector up to lock the probe and air detector into the sampler assembly.

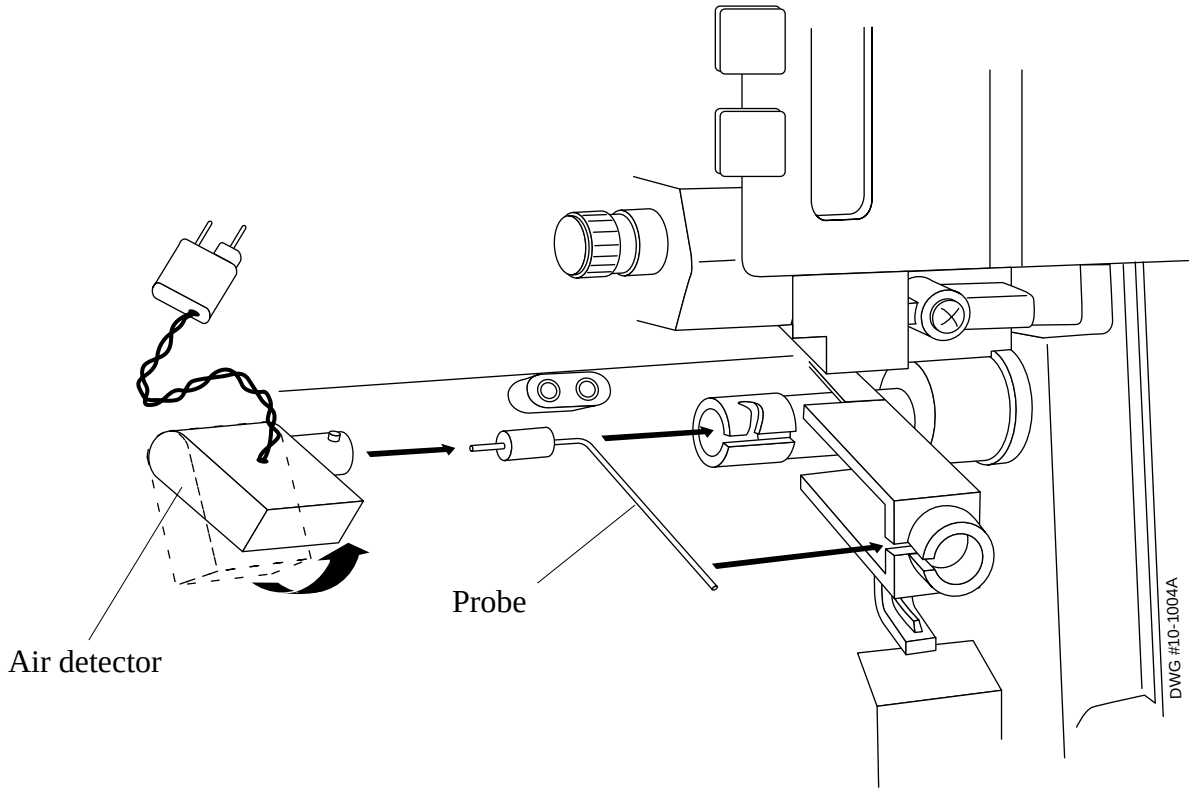


Figure 4.15 Replacing Probe and Air Detector

10. **If changing the probe, do this step; if not skip to next step.** Replace the capillary adapter over the end of the probe. To make the operation easier, push the probe arm back so that the probe extends (1/2 in or 12 mm) beyond the edge. The probe must go through the center hole of the adapter to work probably.
11. Reconnect the air detector's sample line to the sensor module.
12. Reconnect the 2-prong cable back into outlet.
13. Close the door and press the Continue key (soft key).
14. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.

4.2.14 Sensor Module Replacement

If the sensor module becomes damaged, replace it. Use the following procedure when you need to replace it.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. When the cycle is completed, **POWER DOWN THE ANALYZER**. Open the door.
3. Remove the reference electrode (see Section 4.2.7); the SO_2 sensor (see Section 4.2.8); and the air detector's sample line (see Section 4.2.13).
4. Press the tab on the sensors to remove them.

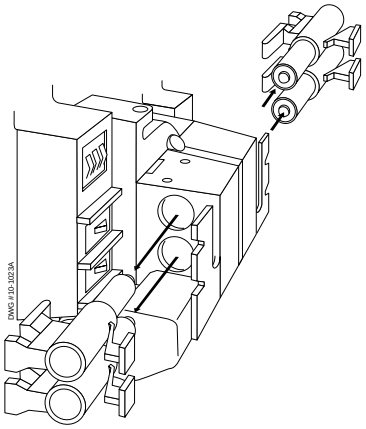


Figure 4.16 Removing the Sensors

5. Disconnect the air detector's sample line.
6. Push the 2 locking levers to the vertical position.

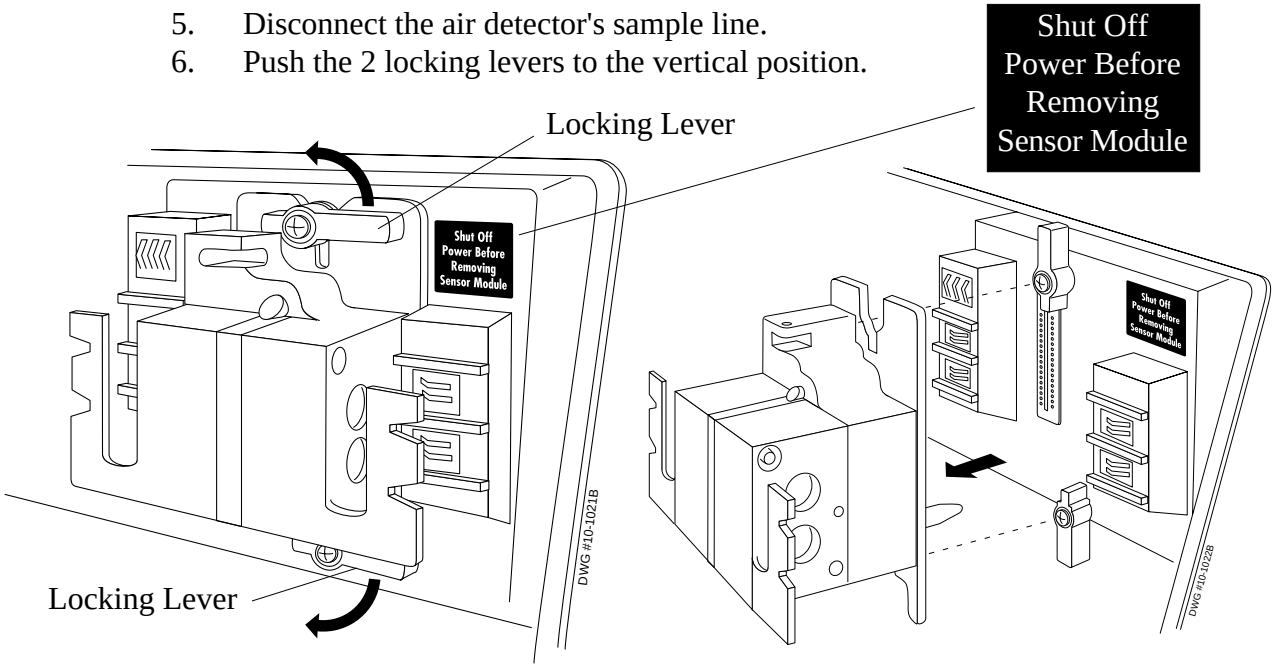

Shut Off Power Before Removing Sensor Module
Locking Lever
Shut Off Power Before Removing Sensor Module
Locking Lever
DWG #10-1021B
Shut Off Power Before Removing Sensor Module
DWG #10-1022B

Figure 4.17 Unlocking and Removing the Sensor Module

7. Remove the sensor module; pull it straight out.
8. Guide the new sensor module into place so that it fits flat.
9. Push the 2 locking levers to the horizontal position.
10. Replace sensors back into their appropriate place in the sensor module; the sensor clicks into position.

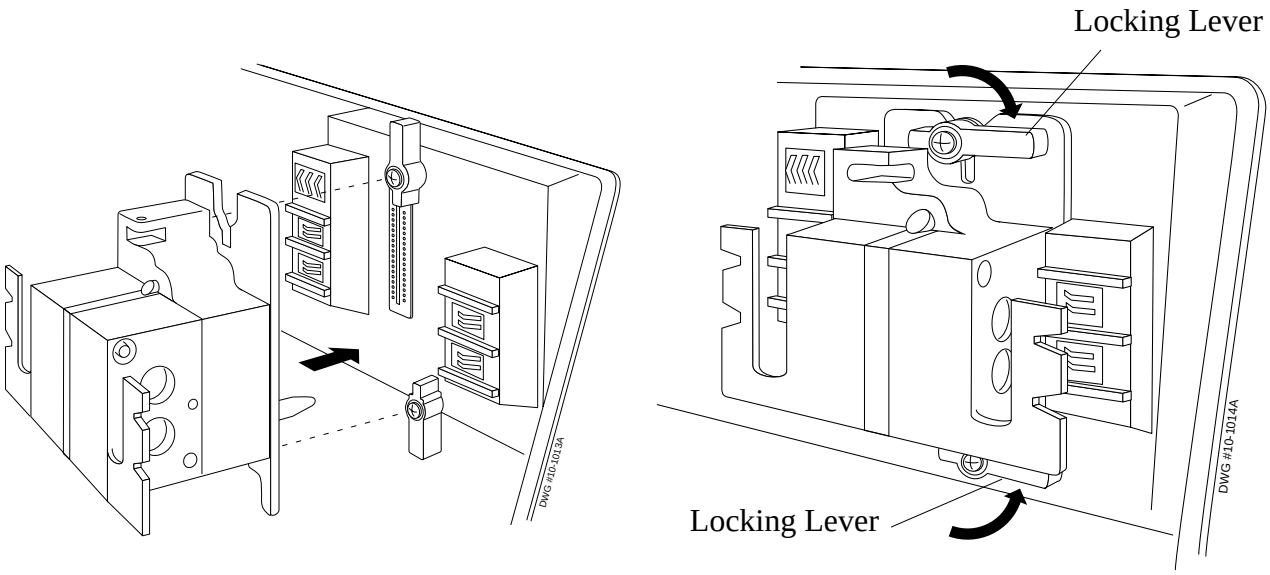


Figure 4.18 Replacing and Locking the Sensor Module

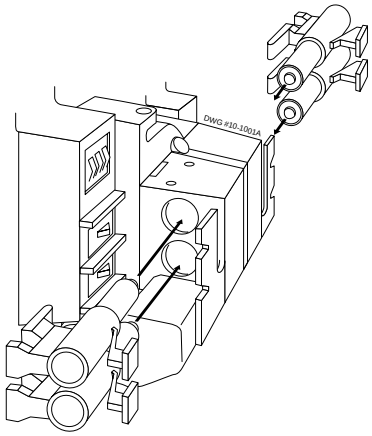


Figure 4.19 Replacing the Sensors

11. Replace the reference electrode (see Section 4.2.7); the SO_2 sensor (see Section 4.2.8); and the air detector's sample line (see Section 4.2.13).
12. Close the door.
13. Power up the analyzer.
14. Calibrate the analyzer.

4.3 Display/Cabinet Cleaning

Cleaning the Display: Clean the display screen with a damp (not wet) lint-free cloth. For a heavy buildup, use a liquid glass cleaner sprayed onto a lint-free cloth first, never spray directly onto the display. If available, prepackaged screen wipes can also be used.

Cleaning the Cabinet: Clean the cabinet with a damp (not wet) lint-free cloth. Do not use aerosol sprays, solvents, or abrasives that might damage the finish.

5 Troubleshooting

This section describes the status screens, error codes, and Service Menu and explains the troubleshooting procedures for the Stat Profile pHOx Analyzer.

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, capillary adapter, probe, sensor module, etc.) with care. Gloves and protective clothing are recommended.

5.1 Troubleshooting Procedures

The recommended troubleshooting procedures use the most logical and direct steps to resolve the error code. The solutions are set up in a block format which lists groups of steps to perform in order to restore operation. The steps are also organized to prevent unnecessary parts replacement, such as sensors and tubing, until the more common causes for an error have been checked.

In the case of multiple error codes, those errors which apply to flow are at the top of the hierarchy. In most cases, when you resolve the flow error codes, the other errors will be resolved as well.

If the recommendations given here do not resolve the problem, contact Nova Technical Services for troubleshooting assistance. It is helpful to have printed or written down the error codes, flow times, and slope performance numbers.

FOR TECHNICAL ASSISTANCE, CALL TOLL FREE:

1-800-545-NOVA

5.2 Stat Profile pHOx 2-Point Calibration Sequence

The calibration sequence is outlined in Table 5.1 according to the order in which the various calibration standards are brought into the system for slope determinations, flow checks, etc.

Table 5.1 Stat Profile pHOx 2-Point Calibration Sequence

Fluid	Function
	Sequence Start
Std A	Standard A readings for AD1, AD2, AD3, AD4, Hct, pH, PCO_2, PO_2, Na^+
Std B	Standard B readings for pH and PCO_2
Air	Air reading for PO_2
Std D	Standard D reading for AD1, AD2, AD3, AD4, Hct, pH, Na^+
Std C	Standard C reading for pH
	Sensor Slopes are calculated
	ADT thresholds are calculated
	Initialization
	End Calibration

When you troubleshoot flow problems, it is important to view the system as a whole. This means that you must consider all of the various components that interact in order to transport fluids throughout the system. These components include the pump, sampler probe, fluid fountain, rotary valve, pinch valves, and tubing.

The information in this section, along with an understanding of the flow path components and their functions, will give you the knowledge and tools you will need to resolve most of the problems you will encounter.

Rapid Reference Guide for Resolving Quality Control Problems

pH	
Results High	• Control Material not at 25°C. • Check for lowsensor slope (<9.5) • Condition pH sensor with pH Conditioning Solution • Check for low fluid pack
Results Low	• Condition sensor module with whole blood • Check for low fluid pack
PO_2	
Results High	• Control Material below 25°C. • Check for air leak in system
Results Low	• Control Material above 25°C. • Clean probe/preheater • Run deproteinizing solution • Check waste line for restrictions • Change membrane
PCO_2	
Results High	• Control Material below 25°C. • Check for low slope • Change membrane • Change sensor
Results Low	• Control Material above 25°C. • Debubble sensor • Condition sensor module with whole blood
Combination Problems	
Gases low/pH high on controls	• Confirm controls temp is not > 25°C
Gases high/pH low on controls	• Confirm controls temp is not < 25°C
Gases consistently out	• Check barometer

5.3 Status Codes

Table 5.3 lists the analyzer's status codes and the corrective action.

Table 5.3 Stat Profile pHOx Status Codes

Status Code	Corrective Action
01 pH Slope 02 pH Instability 03 pH Overload 04 pH Drift	1. Recalibrate. 2. Condition pH sensor. (See Section 5.4.) 3. Replace pH sensor.
11 *P*CO_2 Slope 12 *P*CO_2 Instability 13 *P*CO_2 Overload 14 *P*CO_2 Drift	1. Recalibrate. 2. Replace *P*CO_2 membrane cap (2 times if necessary) 3. Replace *P*CO_2 sensor.
15 *P*CO_2 Dependency	1. Recalibrate pH sensor. 2. Condition pH sensor. 3. Replace pH sensor.
21 *P*O_2 Slope 22 *P*O_2 Instability 23 *P*O_2 Overload 24 *P*O_2 Drift	1. Recalibrate. 2. Replace *P*O_2 membrane cap (2 times if necessary). 3. Replace *P*O_2 sensor.
25 *P*O_2 Delta Millivolts	1. Recalibrate. 2. Replace Reagent Cartridge and recalibrate.
31 *S*O_2 Slope 32 *S*O_2 Instability 33 *S*O_2 Overload 34 *S*O_2 Drift	1. Recalibrate. 2. Clean *S*O_2 sensor. 3. Replace *S*O_2 sensor.
35 *S*O_2 Dependency	1. Recalibrate Na^+ and Hct sensors. 2. Replace Na^+ sensor.
41 Hb Slope 45 Hb Dependency	1. Recalibrate Hct, *S*O_2 sensors.

Table 5.3 Stat Profile pHOx Status Codes (Cont.)

Status Code	Corrective Action
For Hematocrit	
51 Hct/Det Slope 52 Hct/Det Instability 53 Hct/Det Overload 54 Hct/Det Drift	1. Recalibrate. 2. Clean sensor module. 3. Replace sensor module.
55 Hct/Det Dependency	1. Recalibrate Na^+ sensor. 2. Replace Na^+ sensor.
If air detector problem, check the Error Log to see which air detector has the problem.	
Air detector 1	1. Run Flowpath Cleaning cycle. 2. Recalibrate. 3. Replace air detector
Air detector 2 or 3	1. Clean sensor module. 2. Replace sensor module.
Air detector 4	1. Run Flowpath Cleaning cycle. 2. Recalibrate. 3. Replace reference electrode.
61 Na^+ Slope 62 Na^+ Instability 63 Na^+ Overload 64 Na^+ Drift	1. Recalibrate. 2. Replace Na^+ sensor.
71 Std A Flow 72 Std B Flow 73 Std C Flow 74 Std D Flow	1. Flush flow path and prime standard. 2. Replace reagent pack.
75 Flowtime 76 Sample Flow 77 Air Flow	1. Check flowpath for proper operation.
78 Back Flow	1. Check waste line flowpath for proper operation. 2. Refer to Operator Flow Test. See Section 5.5.1.

Table 5.3 Stat Profile pHOx Status Codes (Cont.)

Status Code	Corrective Action
79 Insufficient Sample	1. Verify that you are running the sample in the correct analysis mode and that you have sufficient sample volume. 2. Verify a clot has not been aspirated into the flow path. If yes, flush the flowpath and rerun the controls.
81 Ctrl 1 Flow 82 Ctrl 2 Flow 83 Ctrl 3 Flow	1. Check control pack.
91 Barometer 92. Printer 93. Temperature 94 Communication 95 Hardware 96 Hardware 97 Software 98 Schedule QC	1. Call Nova Technical Service.

5.4 pH Conditioning

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Open the door and locate the pH sensor.
3. Remove the sensor from the sensor module by pinching the front and rear of the sensor clip.
4 Fill bottom chamber of sensor conditioning holder (PN 09458) with pH conditioning solution (PN 23397).
5. Immerse sensor tip in conditioning solution to soak. The pH sensor is conditioned for 15 minutes.
6. Remove sensor and rinse tip with deionized water.
7. Dry tip with lint-free tissue.
8. Dry flow cell with cotton swab covered with lint-free tissue.
9. Insert the pH sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
10. Press the Continue key (soft key).
11. A message displays, Priming Flow Path. Please wait until the time bar completes.
12. Recalibrate.

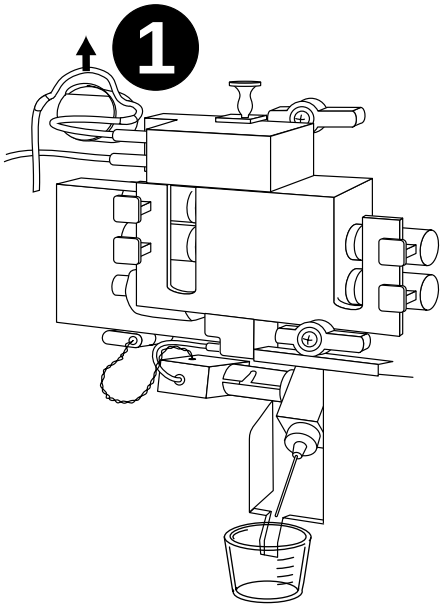
5.5 Troubleshooting Flow Problems

5.5.1 Operator Flow Test

The flow test verifies that fluid can be pulled through the system from the probe. If water cannot be pulled through the system, a clog or leak exists. The procedure for the flow test and sensor module back flush is diagramed on the next 2 pages.
This procedure is also used as a corrective action for Status Code 78 Back Flow.

Operator Flow Test

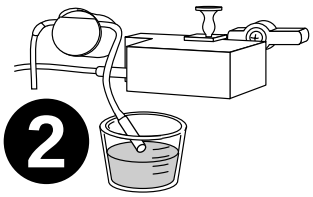
From Ready→Service→System Test→Customer Flow Test



1 - Lift the tubing out of the Waste solenoid.
- If tubing remains pinched, roll it between fingers to loosen.
- Place the sample probe in a cup of water.

Is fluid flow noticed in the waste line tubing?

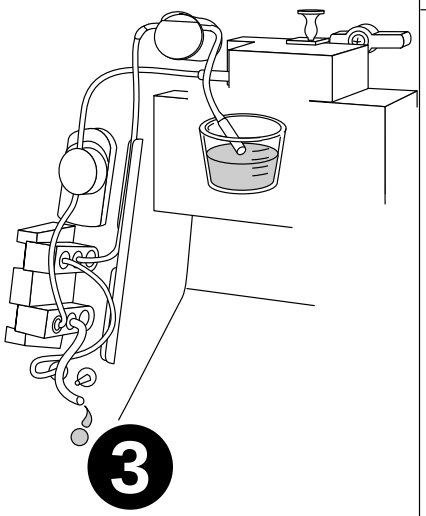
A. IF YES, call your Nova Service Representative.
B. IF NO, go to Step 2.



2 - Disconnect the Waste (W) from the Reference Electrode.
- Place this end of the W tubing into a cup of water.

Is fluid flow seen in the Waste line tubing?

A. IF YES, press "PUMP" to turn off the pump motor.
Go to the next page,
"Sensor Module Back Flush" procedure.
B. IF NO, go to Step 3.



3 - Disconnect the Waste line tubing from the front panel port.
- Place this end of the tubing over a gauze to prevent spilling.
- Aspirate water from the same location as in Step 2 above.

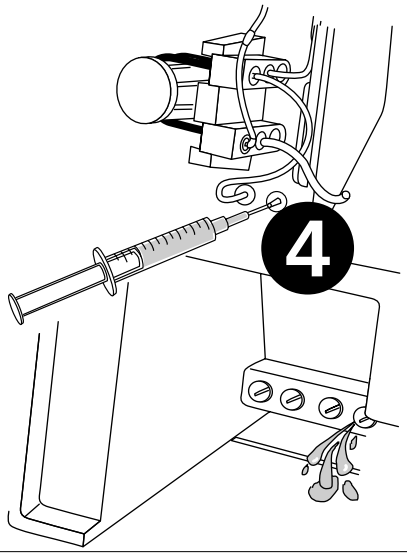
Is fluid seen exiting the Waste tubing end you just disconnected?

A. IF YES, go to Step 4.
B. IF NO, Replace the W/R Tubing Harness (P/N 23023)

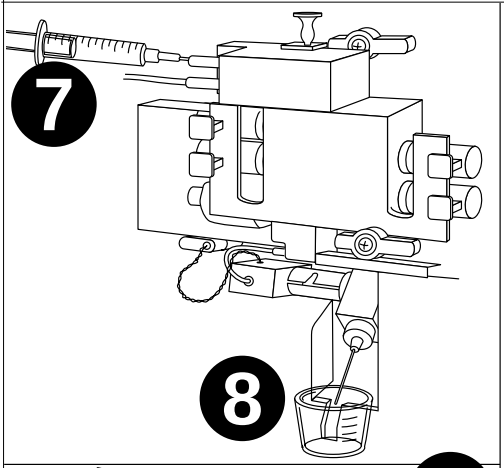
4 - Press the "PUMP" key to stop the Pump Motor
- Remove the Reagents Cartridge from the unit.
- Install the flush adapter.
- Place the flush adapter tubes into an empty beaker.
- Inject water to the front panel Waste port.
- Water should flow through the adapter waste tube.
(Adapter waste line is last to the right)

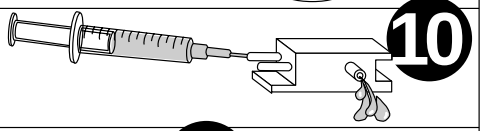
* Loss of Reference flow will change the flow rate. Reference solution will flow at a rate of 1 -2 drops/second during a pumping cycle.

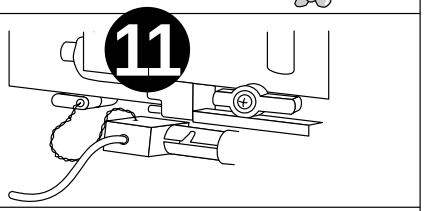
** If this tubing cannot be flushed call your Nova Service Representative. If tubing flushes easily, change the Reagents Cartridge. In a small number of cases the original problem may have been poor alignment of the Reagents Cartridge.

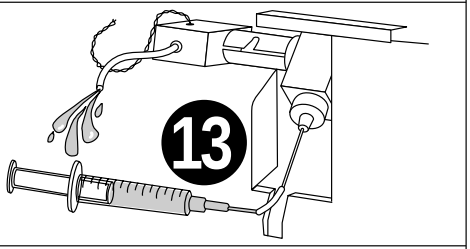


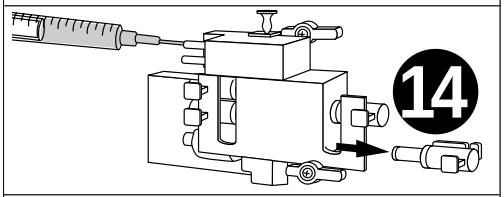
Sensor Module Back Flush Procedure

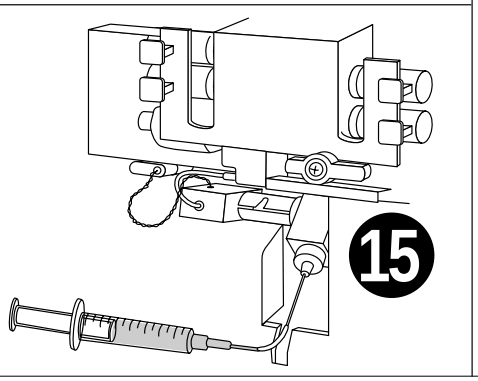












⑤ If you are starting from the Operator Flow Test
-Turn the Pump OFF by pressing the "PUMP" key.

⑥ If you are starting from the Ready Screen
- Press Service, System Test and select the Operator Flow Test.
- Turn the pump OFF as in Step 5.

❼ Connect a syringe filled with water to the Reference electrode waste port.

❽ Back flush the flow path by injecting the water.
Caution: Place a gauze or towel at the sample probe tip to receive the obstruction or water.

⑨ If the water easily flushes through the sensor module, you may have an air leak into the flowpath. This will be from an interconnect tubing, failed membrane, or poorly seated electrode. Go to Step 15.

❿ If water does NOT exit the sample probe.
- Lift the Reference electrode off the sensor module.
- Flush the Reference electrode.

If it flows freely, confirm that the interconnect tubing is properly positioned and reinstall the Reference Electrode.

⓫ Disconnect the Air Detector from the bottom of Sensor Module.

⑫ Inject water into the W port of the Reference Electrode.
Does water flow through the sensor module?
IF YES, go to Step 13.
IF NO, go to Step 14.

⓭ - Connect the syringe to the Sample Probe tip.
- Inject water through the Probe

Water should exit the Air Detector (ADT) tubing.
IF NO flow is noted, flush the ADT and probe separately.
IF the water flows easily, the seal between the ADT and probe may be leaking. Replace the Air Detector.

⓮ (NO from Step 12) The obstruction lies in the flowcell. While continuing to inject, remove one electrode at a time. Starting with the bottom electrode. When water starts to flow either the obstruction flushed into the flowcell or the electrode just removed was the cause. Re-membrane if needed. Dry the flowcell before re-inserting the electrode.

⓯ (From Step 9) Connect the syringe with water to the sample probe tip. Reconnect the Reference electrode Waste line. Apply a slight pressure to the syringe. Look for water entering a flowcell, electrode cap, or leaking from the interconnect tubing. Replace the membrane, or tubing as required.

If the above does not identify the problem, please contact your Nova Service Representative.

5.5.2 Flushing the Reference Electrode

1. Remove the W-line and R-line from the reference electrode.
2. Lift the reference electrode off the sensor module by pulling up on the locking pin that is on the top of the reference electrode.
3. Connect a syringe (Probe Cleaning Syringe PN 02702) filled with water, that has a length of tubing attached to it, to the W-port of the reference electrode. While covering the R-port with your finger, push water through the electrode so that the water flows out of the flow cell port. Repeat by attaching the syringe to the R-port and covering the W-port while pushing water through the electrode.

6 Service Menu

To display the Service Menu, press Service (soft key) on the Operational Menu. Then enter your password. The Service Menu allows access to the following options:

- System Test
- Analog Input - Real time mV
- Sensor Subsystem (Calibration and Analysis data)
- Printer Menu
- Error Log
- Communications tests
- Versions List

6.1 Sensor Subsystem Screens

From the Service Menu, select Sensor Subsystem and press Enter. You can scroll through the 8 sensor screens by pressing Next Screen (soft key). The following are the 8 status screens:

- pH Sensor
- PCO_2 Sensor
- PO_2 Sensor
- Na Sensor
- SO_2 LED 1
- SO_2 LED 2
- Hct Sensor
- Air Detectors

A printed record for each screen can be obtained by pressing Print (soft key). All the diagnostic information on the screen is printed (standards, slope, concentrations, etc.).

6.1.1 Running a Flow Test and Checking the Rotary Valve Operation

A flow test can be run on each standard. To run a flow test, display the System Test screen and select Service Flow Test (soft key), Run Test (soft key). When the test is completed, the Flow Test Results screen is displayed with the flow results for all standards.

6.1.2 Checking the Sampler

The sampler can be in any one of several positions: capillary, syringe, air, or home. These positions can be manually checked by selecting the Sampler option on the System Test screen.

1. Select Sampler with arrow keys.
2. Press Enter.
3. A pop-up window is displayed over the screen. Using the arrow keys, select a sampler position.
4. After the sampler travels to the selected position, check that the sampler is positioned correctly.

6.1.3 Checking the Pump

There are 4 pump speeds: slow, medium slow, medium fast, and fast. These speeds can be manually checked by selected the Pump option on the System Test screen.

1. Select Pump with arrow keys.
2. Press Enter.
3. A pop-up window is displayed over the screen. Select one of the 4 pump speeds with the arrow keys. Then press Enter to activate the pump.
4. Check that the pump is working and pumping fluid.
5. To stop the pump, repeat steps 1 thru 3 and select the stop option with the arrow keys, Then press Enter to stop the pump.

6.1.4 Checking the Waste Valve

The waste valve can be checked by selected Waste valve with the arrow keys on the System Test screen. Press Enter to open or close the valve.

6.1.5 Checking the Reference Valve

The reference valve can be checked by selected Ref. valve with the arrow keys on the System Test screen. Press Enter to open or close the valve.

6.1.6 Checking the SO_2 LEDs

The SO_2 LEDs can be checked by selected SO_2 LEDs with the arrow keys on the System Test screen. Press Enter to turn the lights on or off.

6.1.7 Checking the Air Detectors

The air detectors can be checked by setting the X-level of the air detector of interest and then enabling the air oscillator. From the System Test screen, select X-level with the arrow keys then press Enter. Select the desired air detector then press Enter. Select the air oscillator with the arrow keys then press Enter to turn the detector on or off.

6.2 Analog Input

From the Service Menu, select the Analog Input option and press Enter. The Analog Input screen is displayed with the 25 channels and the millivolt readings.

6.3 System Test

From the Service Menu, select System Test and press Enter. The System Test screen displays millivolt readings for all sensors. From the System Test screen, you can check the sampler, rotary valve, pump, waste valve, reference valve, ADT's and SO_2 LED's.

6.4 Printer Menu

From the Service Menu, select the Printer Menu option and press Enter. The Printer Menu screen is displayed with 4 options: Printer Enabled, Print System Error Log, Print System Dump, or Character Set Test.

1. Select an option with the arrow keys.
2. Press Enter.
   - Printer Enabled or Disabled, press enter to enable or disable the printer.
   - Print System Error Log, press Enter to print the error logs for the analyzer.
   - Print System Report, press Enter to print all the setup, calibration, and analysis data.
   - Character Set Test, press Enter to print all characters test pattern of the printer.
3. Press Exit (soft key) to return to the Service Menu.

6.5 Error Log

From the Service Menu, select the Error Log option and press Enter. The Error Log screen is displayed with errors displayed in chronological order. To go to the next or previous error log pages, press the Page Down or Page Up (soft keys). To print the error log, select Printer Menu from the Service Menu.

6.6 Communications Test

From the Service Menu, select the Communications Test option and press Enter. The Communications Tests screen is displayed with the 2 options: Loopback Tests and Send test characters.

LoopBack Test

1. Select the Loopback Tests option on the Communications Tests screen.
2. Press Enter to display the Loopback Tests screen.
3. Use the arrow keys to select a port: Bar Code, Computer, and COOX.
4. Install the loopback plug.
5. Press Enter to start the test.

Send Test Characters

1. Select the Send Test Characters option on the Communications Tests screen.
2. Press Enter to display the Send Test Characters screen.
3. Use the arrow keys to select a port: Bar Code, Computer, and COOX.
4. Press Send Characters (soft key) to send the character packet.

6.7 RS-232 Serial Ports

The Stat Profile pHOx Analyzer's communications interface is an asynchronous RS-232C compatible serial interface. The analyzer can transfer analytical results to an external device (CO-Oximeter, PDM, computer, etc.). There are 3 serial communication ports and 1 bar code reader port located at the back of the analyzer. Each port uses a standard DB9P male connector to connect the analyzer to external devices. Table 6.1 describes the layout of the pHOx's 9-pin connectors, and Table 6.2 assigns the connections.

Table 6.1 External Device 9-pin Connector

Pin Assignment	Signal Designation	Circuit Source	Function
1	RCD	EXTERNAL	Data Carrier Detect
2	RXD	EXTERNAL	Received data
3	TXD	ANALYZER	Transmitted data
4	DTR	ANALYZER	Data Terminal Ready
5	GND	-	Signal Ground
6	DSR	EXTERNAL	Data Set Ready
7	RTS	ANALYZER	Request to Send
8	CTS	EXTERNAL	Clear to Send
9	RI	EXTERNAL	Ring Indicator

Table 6.2 Serial Port and Device Connections

Serial Port	Device
Bar Code Port	Bar Code Scanner
COM 1	Nova's use only
COM 2	PDM/Computer
COM 3	CO-Oximeter

The analyzer can transmit or receive data at any one of 3 bauds: 4800, 9600, and 19200. Word length is fixed at 7 or 8 bits. Configure the ports from the Setup Menu. The following are the setup options with the defaults in bold:

Baud	4800, **9600**, 19200
Stop Bits	**1** or 2
Parity	**None**, Odd, Even
Data Bits	7, **8**

6.7.1 CO-Oximeter Interface

The Stat Profile pHOx Analyzer can interface with the Nova CO-OXIMETER via the serial communications port (COM 3) to receive CO-Ox results.

6.7.2 PDM/Computer Interface

The Stat Profile pHOx Analyzer can interface with the Nova PDM or an external computer via the serial communications port (COM 2) to transmit patient results. See Section 7.0.

6.7.3 Bar Code Scanner Port

An optional bar code scanner can be connected to the Stat Profile pHOx Analyzer to input patient data. The patient information can be programmed onto a bar code sticker that is attached to the patient's sample. Then the patient's information can be easily inputted via the bar code scanner into the analyzer.

Follow this procedure to set up the bar code scanner.

1. Calibrate the analyzer if it is not calibrated.
2. Plug the bar code scanner into the Bar Code Scanner Port (DB-9P) on the back of the pHOx.
3. Listen for a tone. This indicates that the bar code is ready.
4. Start a sample analysis (syringe only).
5. When the Sample Information screen is displayed, scan in following as needed:
   - Accession number
   - Patient ID number (English only, alphanumeric)
   - Operator ID
   - Patient Temperature
6. Continue the analysis.

6.7.4 External Keyboard

Follow the directions of the insert sheet that comes with the keyboard.

7 Introduction

This document describes how the Nova pHOx transmits data to an external computer. Data transmission involves a low-level protocol and a high-level protocol. The low-level protocol is concerned with establishing communication, detecting errors, and sending and receiving messages. It is not concerned with message content. The high-level protocol is concerned with message content.

The protocols used are designed to conform to specifications published by the American Society for Testing and Materials (ASTM). Copies of the specifications can be obtained by contacting ASTM:

ASTM
100 Barr Harbor Drive
West Conshohocken, PA 19428-2959
USA
phone: 610-832-9585
FAX: 610-832-9555

The low-level protocol used by the Nova pHOx is designed to conform to **ASTM E1381-91**. This document is concerned with the high level protocol only.

The following information pertains to pHOx only samples, pHOx only calibration, pHOx Only QC, and Combined results.

The pHOx also transmits COOX only data. Those records are specified by the COOX ASTM specification

7.1 High-Level Protocol

The high-level protocol used by pHOx is designed to conform to **ASTM E1394-91**.

The tables that follow describe the data records that are sent by pHOx. The column "ASTM REF" lists the section of the ASTM E1394-91 specification that defines the field. The column "ASTM NAME" lists the field name that appears in the ASTM specification.

Unless otherwise noted, any field that involves date and time conforms to section 6.6.2 of ASTM 1394-91. Each record ends with a carriage return.

7.1.1 Header Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
7.1.1	Record Type ID	Single character: “H”
7.1.2	Delimiter Definition	Standard delimiters: |\^&
7.1.3	Message Control ID	*Not Used*
7.1.4	Access Password	*Not used*
7.1.5	Sender Name or ID	NOVA^pHOx^vv..vv^dd Where ‘vv..vv’ is the version of pHOx software, and ‘dd’ is Analyzer Identification # set by the pHOx operator.
7.1.6	Sender Street Address	*Not used*
7.1.7	Reserved Field	*Not used*
7.1.8	Sender Telephone Number	*Not used*
7.1.9	Characteristics of Sender	*Not used*
7.1.10	Receiver ID	*Not used*
7.1.11	Comment or Special Instruction	*Not used*
7.1.12	Processing ID	*Not used*
7.1.13	Version No.	Version of ASTM Spec., single char.: “1”
7.1.14	Date and Time of Message	Date and time at which message was transmitted. (This is not the time of the analysis or calibration.)

7.1.2 Patient Information Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
8.1.1	Record Type	Single character: “P”
8.1.2	Sequence Number	Single character: “1”. (This will always be “1” because there will be only one patient record per message.) **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
8.1.3	Practice Assigned Patient ID	*Not used*
8.1.4	Laboratory Assigned Patient ID	Patient ID # if available; otherwise, blank. For patient samples, Patient ID # is available if and only if it was entered by the pHOx operator. For QC samples and for calibrations, this will be blank. **NOTE:** This is the last field that is used in this record.
8.1.5	Patient ID No. 3	*Not used*
8.1.6	Patient Name	Last^ First^ Middle
8.1.7	Mother’s Maiden Name	*Not used*
8.1.8	Birthdate	*Not used*
8.1.9	Patient Sex	*Not used*
8.1.10	Patient Race-Ethnic Origin	*Not used*
8.1.11	Patient Address	*Not used*
8.1.12	Reserved Field	*Not used*
8.1.13	Patient Telephone Number	*Not used*
8.1.14	Attending Physician ID	*Not used*
8.1.15	Special Field 1	*Not used*

8.1.16	Special Field 2	*Not used*
8.1.17	Patient Height	*Not used*
8.1.18	Patient Weight	*Not used*
8.1.19	Patient's Known or Suspected Diagnosis	*Not used*
8.1.20	Patient Active Medications	*Not used*
8.1.21	Patient's Diet	*Not used*
8.1.22	Practice Field No. 1	*Not used*
8.1.23	Practice Field No. 2	*Not used*
8.1.24	Admission and Discharge Dates	*Not used*
8.1.25	Admission Status	*Not used*
8.1.26	Location	*Not used*
8.1.27	Nature of Alternative Diagnostic Code and Classifiers	*Not used*
8.1.28	Alternative Diagnostic Code and Classification	*Not used*
8.1.29	Patient Religion	*Not used*
8.1.30	Marital Status	*Not used*
8.1.31	Isolation Status	*Not used*
8.1.32	Language	*Not used*
8.1.33	Hospital Service	*Not used*
8.1.34	Hospital Institution	*Not used*
8.1.35	Dosage Category	*Not used*

7.1.3 Test Order Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
9.4.1	Record Type ID	Single character: "O"
9.4.2	Sequence Number	Single character: "1". (This will always be "1" because Ultra will send only one order per message.) **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
9.4.3	Specimen ID	For patient samples, accession # if available; otherwise, blank. For QC analyses, the ID is one of the following: "QC0 Proficiency" "QC1 Level 1 Internal" "QC2 Level 2 Internal" "QC3 Level 3 Internal" "QC4 Level 1 External" "QC5 Level 2 External" "QC6 Level 3 External" "QC7 Level 4 External" "QC8 Level 5 External" For calibrations, this field is blank.
9.4.4	Instrument Specimen ID	Sample Number from pHOx's Sample Number Counter.
9.4.5	Universal Test ID	*Not used*
9.4.6	Priority	*Not used*
9.4.7	Requested/Ordered Date and Time	*Not used*
9.4.8	Specimen Collection Date and Time	*Not used*
9.4.9	Collection End Time	*Not used*
9.4.10	Collection Volume	*Not used*
9.4.11	Collector ID	*Not used*

9.4.12	Action Code	*Not used*
9.4.13	Danger Code	*Not used*
9.4.14	Relevant Clinical Information	*Not used*
9.4.15	Date/Time Specimen Received	*Not used*
9.4.16	Specimen Descriptor	For patient samples, this will be the sample type ("Arterial", "Venous", "Capillary", or "Mixed Venous"). For QC samples, this will be "Control". For calibrations, this will be "Cal".
9.4.17	Ordering Physician	*Not used*
9.4.18	Physician's Telephone Number	*Not used*
9.4.19	User Field No. 1	*Not used*
9.4.20	User Field No. 2	*Not used*
9.4.21	Laboratory Filed No. 1	*Not used*
9.4.22	Laboratory Filed No. 2	*Not used*
9.4.23	Day/Time Results Reported or Last Modified	*Not used*
9.4.24	Instrument Charge to Computer System	*Not used*
9.4.25	Instrument Section ID	*Not used*
9.4.26	Report Types	'F' - final results (Results do not require remote review.) 'P' - remote review
9.4.27	Reserved Field	*Not used*
9.4.28	Location or Ward of Specimen Collection	*Not used*
9.4.29	Nosocomial Infection Flag	*Not used*

9.4.30	Specimen Service	*Not used*
9.4.31	Specimen Institution	*Not used*

7.1.4 Result Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
10.1.1	Record Type	Single character: "R"
10.1.2	Sequence Number	Counts the parameters sent for this order; '1' for the first parameter, '2' for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
10.1.3	Universal Test ID	Four or five components; the first three are not used (see sections 6.6.1.1-6.6.1.3 of ASTM E1394-91). The fourth is a parameter name assigned by NOVA. The fifth, if present, will be the parameter type; it will be one of the following: C - Calculated D - Default E - Entered M - Measured T - Temperature Corrected **NOTE:** Parameter names are listed elsewhere in this document.
10.1.4	Data or Measurement Value	Value of the parameter as an ASCII string.
10.1.5	Units	Abbreviation of units.
10.1.6	Reference Ranges	*Not used*

10.1.7	Result Abnormal Flags	HH - Above High Panic value H - Above High Reference value L -Below Low Reference value LL - Below Low Panic value > - Above the range of the analyzer < - Below the range of the analyzer When calibration data is sent, this field will be one of the following: A - (abnormal) channel is not calibrated N - (normal) channel is calibrated **NOTE:** When this field is blank, at least one of the following is true: a. A reference range has been set, and the measurement is within the reference range. b. A reference range has not been set, but a panic range has been set, and the measurement is within the panic range. c. Neither a reference range nor a panic range has been set. d. The sample is a Q.C. sample.
10.1.8	Nature of Abnormality Testing	*Not used*
10.1.9	Result Status	'F' - final results (Results do not require remote review.) 'P' - remote review
10.1.10	Date of Change of Instrument Normative Values or Units	*Not used*
10.1.11	Operator Identification	Operator ID#
10.1.12	Date/Time Test Started	Date&time at which the analysis or cal. started.
10.1.13	Date/Time Test Completed	*Not used*
10.1.14	Instrument Identification	pHOx Analyzer ID.

7.1.5 Comment Record

Comment Record(s) will immediately follow a Test Order if and only if there were any errors during sample analysis. There will be one Comment Record for each error.

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
11.1.1	Record Type	Single character: “C”
11.1.2	Sequence Number	Counts the comments sent for this order; ‘1’ for the first comment, ‘2’ for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
11.1.3	Comment Source	Single character: “I”
11.1.4	Comment Text	An error code followed by descriptive text. (e.g., “25 Na Unstable”).
11.1.5	Comment Type	Single character: “I”

7.1.6 Message Terminator Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
13.1.1	Record Type	Single character: “L”
13.1.2	Sequence Number	For this record type this is always “1”. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
13.1.3	Termination Code	One of the following: N - normal termination T - sender aborted

7.1.7 Parameter Names

The parameter names listed here are used as *Manufacturer's or Local Code* (see ASTM E1394-91 sec. 6.6.1.4). They are used to create the Universal Test ID field of the result record (see Result Record above and see ASTM E1394-91 sec. 10.1.3).
In most cases only a subset of these parameters will be transmitted. For example, during setup of the pHOx, the operator can disable transmission of any or all of the following:

- Analysis diagnostic data
- Calibration diagnostic data
- Calibration drift data

Parameter Name	Units	Description
Na+	mmol/L	Sodium Concentration
Na+_SM	mV	Sodium Sample Millivolts
Na+_M1	mV	Sodium Millivolts #1
Na+_M2	mV	Sodium Millivolts #2
Na+_M4	mV	Sodium Millivolts #4
Na+_SL	*None*	Sodium Slope
Na+_V2	*None*	Sodium Calibration Std. Value #2
Hct	%	Hematocrit Concentration
Hct_SM	mV	Hematocrit Sample Millivolts
Hct_M1	mV	Hematocrit Millivolts #1
Hct_M2	mV	Hematocrit Millivolts #2
Hct_M4	mV	Hematocrit Millivolts #4
Hct_SL	*None*	Hematocrit Slope
pH	*None*	pH Concentration

pH_SM	mV	pH Sample Millivolts
pHTC	*None*	pH Conc. Corrected to Patient Temperature
pH_M1	mV	pH Millivolts #1
pH_M2	mV	pH Millivolts #2
pH_M3	mV	pH Millivolts #3
pH_M4	mV	pH Millivolts #4
pH_SL	*None*	pH Slope
pH_D1	*None*	pH Drift #1
pH_D2	*None*	pH Drift #2
pH_V1	*None*	pH Calibration Std. Value #1
pH_V2	*None*	pH Calibration Std. Value #2
PO2	mmHg, kPa	$P\mathrm{O}_2$ Concentration
PO2TC	mmHg, kPa	$P\mathrm{O}_2$ Conc. Corrected to Patient Temperature
PO2_SM	mV	$P\mathrm{O}_2$ Sample Millivolts
PO2_M1	mV	$P\mathrm{O}_2$ Millivolts #1
PO2_M2	mV	$P\mathrm{O}_2$ Millivolts #2
PO2_M3	mV	$P\mathrm{O}_2$ Millivolts #3
PO2_SL	*None*	$P\mathrm{O}_2$ Slope
PO2_D1	*None*	$P\mathrm{O}_2$ Drift #1
PO2_V1	*None*	$P\mathrm{O}_2$ Calibration. Gas Value #1

PCO2	mmHg, kPa	PCO_2 Concentration
PCO2_SM	mV	PCO_2 Sample Millivolts
PCO2TC	mmHg, kPa	Corrected PCO_2 Concentration
PCO2_M1	mV	PCO_2 Millivolts #1
PCO2_M2	mV	PCO_2 Millivolts #2
PCO2_SL	*None*	PCO_2 Slope
PCO2_D1	*None*	PCO_2 Drift #1
PCO2_D2	*None*	PCO_2 Drift #2
PCO2_V1	*None*	PCO_2 Calibration. Gas Value #1
PCO2_V2	*None*	PCO_2 Calibration. Gas Value #2
SO2%	*None*	SO_2 Percent
S1_SL	*None*	SO_2 LED #1 Slope
S2_SL	*None*	SO_2 LED #2 Slope
S1_SM	mV	SO_2 LED #1 Sample Millivolts
S2_SM	mV	SO_2 LED #2 Sample Millivolts
S1_M1	mV	SO_2 LED #1 millivolts #1
S1_M2	mV	SO_2 LED #1 millivolts #2
S1_M3	mV	SO_2 LED #1 millivolts #3
S1_M4	mV	SO_2 LED #1 millivolts #4
S2_M1	mV	SO_2 LED #2 millivolts #1
S2_M2	mV	SO_2 LED #2 millivolts #2

S2_M3	mV	SO_2 LED #2 millivolts #3
S2_M4	mV	SO_2 LED #2 millivolts #4
FIO2	%	Percent Fraction Inspired Oxygen
BP	mmHg	Barometric Pressure
TempM	deg C, deg F	Measurement Temperature
TempP	deg C, deg F	Patient Temperature
Hb	g/dL	Hemoglobin
Hb_SL	*None*	Hemoglobin Slope
BE-ecf	mmol/L	Base Excess, Extra-Cellular Fluid
BE-b	mmol/L	Base Excess, Blood
SBC	mmol/L	Standard Bicarbonate
HCO3-	mmol/L	Bicarbonate Ion Concentration
TCO2	mmol/L	Total CO_2
O2Ct	Vol/100mL, mL/dL, mL/L	Oxygen Content
A	mmHg,kPa	Alveolar Air PO_2
a/A	*None*	Alveolar Ratio
AaDO2	mmHg,kPa	Alveolar Arterial Oxygen Gradient
P50	mmHg	PO_2 @ 50% SO_2
O2CAP	Vol/100mL, mL/dL, mL/L	Oxygen Capacity
RI	*None*	Respiratory Index
THb	g/dL, g/L, mmol/L	Total Hemoglobin

O2Hb	% or *None*	Oxyhemoglobin
COHb	%or *None*	Carboxyhemoglobin
MetHb	%or *None*	Methemoglobin
HHb	%or *None*	Reduced Hemoglobin
FO2Hb	% or *None*	Fractional Hemoglobin
PO2/FIO2	mmHg, kPa	
CcO2	mL/dL	capillary oxygen concentration
CvO2	mL/dL	venous oxygen concentration
CaO2	mL/dL	arterial oxygen concentration
AvDO2	mmHg, kPa	arterial-mixed venous oxygen gradient
Qsp/Qt	*None*	physiologic shunt
MTHB	g/dL	Measured tHb for a pHOx Calibration
TTHB	g/dL	Target tHb for a pHOx Calibration
DTHB	g/dL	tHb drift for a pHOx Calibration
puncture_site	None	Entered by user
ventilator_rate/min	None	Entered by user
tidal_volume	None	Entered by user
peep_cpap	None	Entered by user
mode_of_therapy	None	Entered by user

The following are for CO-Ox diagnostics only and will not normally be transmitted:

NumScans_X	*None*
SHb_X	*None*
Turbid_X	*None*

Abs1_X	*None*
Abs2_X	*None*
Abs3_X	*None*
Abs4_X	*None*
Abs5_X	*None*
Abs6_X	*None*
Abs7_X	*None*
Abs8_X	*None*
WL1_X	*None*
WL2_X	*None*
WL3_X	*None*
WL4_X	*None*
WL5_X	*None*
WL6_X	*None*
WL7_X	*None*
WL8_X	*None*
tHbCal_X	*None*
MO2HB_X	% or *None*
TO2HB_X	% or *None*
DO2HB_X	% or *None*
MHHB_X	% or *None*
THHB_X	% or *None*
DHHB_X	% or *None*

7.2 Examples

The following examples do not include any special characters such as ENQ and STX. Also, each line ends before the checksum.

7.2.1 pHOx Only Patient Sample

```
1H|\ ^&|||NOVA^pHOx^i04.07^82||||||||1|20010611125800
2P|1||123456789012345||Mannarino^Alan^J.
3O|1|123456789012345|4||||||||||||Arterial||||||||||F
4C|1|I|55  Hct/Air Det Dependenc|I
5R|1|^^^pH^M|7.484|||||F||123456789012|20010611125600||82
6R|2|^^^PCO2^M|4.9|mmHg||||F||123456789012|20010611125600||82
7R|3|^^^PO2^M|192.2|mmHg||||F||123456789012|20010611125600||82
0R|4|^^^Hb^M^D|14.9|g/dL||||F||123456789012|20010611125600||82
1R|5|^^^Hct^M^D|45|%|||||F||123456789012|20010611125600||82
2R|6|^^^SO2%^M^D|99.8|||||F||123456789012|20010611125600||82
3R|7|^^^pHTC^T|7.484|||||F||123456789012|20010611125600||82
4R|8|^^^PCO2TC^T|4.9|mmHg||||F||123456789012|20010611125600||82
5R|9|^^^PO2TC^T|192.2|mmHg||||F||123456789012|20010611125600||82
6R|10|^^^HCO3-^C|3.7|mmol/L||||F||123456789012|20010611125600||82
7R|11|^^^BE-b^C^D|-14.2|mmol/L||||F||123456789012|20010611125600||82
0R|12|^^^BE-ecf^C|-19.9|mmol/L||||F||123456789012|20010611125600||82
1R|13|^^^TCO2^C|3.8|mmol/L||||F||123456789012|20010611125600||82
2R|14|^^^SBC^C^D|13.9|mmol/L||||F||123456789012|20010611125600||82
3R|15|^^^A^C|146.8|mmHg||||F||123456789012|20010611125600||82
4R|16|^^^a/A^C|1.3|||||F||123456789012|20010611125600||82
5R|17|^^^O2Ct^C^D|21.2|mL/dL||||F||123456789012|20010611125600||82
6R|18|^^^O2CAP^C^D|20.7|mL/dL||||F||123456789012|20010611125600||82
7R|19|^^^TempP^D|37.0|deg C||||F||123456789012|20010611125600||82
0R|20|^^^BP^M|760.8|mmHg||||F||123456789012|20010611125600||82
1R|21|^^^TempM^M|37.0|deg C||||F||123456789012|20010611125600||82
2R|22|^^^FIO2^D|20.9|%||||F||123456789012|20010611125600||82
3R|23|^^^tidal_volume^E|0.2|||||F||123456789012|20010611125600||82
4R|24|^^^peep_cpap^E|15.0|||||F||123456789012|20010611125600||82
5R|25|^^^pH_SM^M|106.85|||||F||123456789012|20010611125600||82
6R|26|^^^PCO2_SM^M|71.33|||||F||123456789012|20010611125600||82
7R|27|^^^PO2_SM^M|-125.66|||||F||123456789012|20010611125600||82
0R|28|^^^Hct_SM^M|928.30|||||F||123456789012|20010611125600||82
1R|29|^^^pH_M1^M|108.89|||||F||123456789012|20010611125600||82
2R|30|^^^PCO2_M1^M|107.41|||||F||123456789012|20010611125600||82
3R|31|^^^PO2_M1^M|-120.28|||||F||123456789012|20010611125600||82
4R|32|^^^Hct_M1^M|2212.11|||||F||123456789012|20010611125600||82
```

```
5R|33|^^^pH_SL^M|10.57|||||F||123456789012|20010611125600||82
6R|34|^^^PCO2_SL^M|9.45|||||F||123456789012|20010611125600||82
7R|35|^^^PO2_SL^M|-7.18|||||F||123456789012|20010611125600||82
0R|36|^^^Hb_SL^M|10.00|||||F||123456789012|20010611125600||82
1R|37|^^^Hct_SL^M|28.64|||||F||123456789012|20010611125600||82
2R|38|^^^S1_SM^M|513.28|||||F||123456789012|20010611125600||82
3R|39|^^^S2_SM^M|583.67|||||F||123456789012|20010611125600||82
4R|40|^^^S1_M1^M|56.57|||||F||123456789012|20010611125600||82
5R|41|^^^S2_M1^M|175.09|||||F||123456789012|20010611125600||82
6R|42|^^^S1_SL^M|8.87|||||F||123456789012|20010611125600||82
7R|43|^^^S2_SL^M|10.03|||||F||123456789012|20010611125600||82
0R|44|^^^puncture_site^E|Brachial Artery|||||F||123456789012|20010611125600||82
1R|45|^^^mode_of_therapy^E|ACV|||||F||123456789012|20010611125600||82
2R|46|^^^ventilator_rate^E|50|||||F||123456789012|20010611125600||82
3L|1|N
```

7.2.2 pHOx Only QC Sample

```
1H|\^&|||NOVA^pHOx^I00.53^123|||||||1|19980827180000
2P|1||123456
3O|1|QC4 Level 1 External|0||||||||||Control||||||||||F
4C|1|I|35  SO2% Dependency|I
5C|2|I|45  Hb Dependency|I
6R|1|^^^H+^M|70.479|nmol/L||||F||1|19980827175800||123
7R|2|^^^PCO2^M|59.8|mmHg||||F||1|19980827175800||123
0R|3|^^^PO2^M|62.3|mmHg||||F||1|19980827175800||123
1R|4|^^^Hb^M||g/dL||||F||1|19980827175800||123
2R|5|^^^Hct^M||%||<||F||1|19980827175800||123
3R|6|^^^SO2%^M||||||F||1|19980827175800||123
4R|7|^^^Na+^M||mmol/L||||F||1|19980827175800||123
5R|8|^^^pH_SM^M|43.290|||||F||1|19980827175800||123
6R|9|^^^PCO2_SM^M|102.995|||||F||1|19980827175800||123
7R|10|^^^PO2_SM^M|-42.850|||||F||1|19980827175800||123
0R|11|^^^Hct_SM^M|2243.885|||||F||1|19980827175800||123
1R|12|^^^Na+_SM^M||||||F||1|19980827175800||123
2R|13|^^^pH_M1^M|28.478|||||F||1|19980827175800||123
3R|14|^^^PCO2_M1^M|88.510|||||F||1|19980827175800||123
4R|15|^^^PO2_M1^M|-115.677|||||F||1|19980827175800||123
5R|16|^^^Hct_M1^M|1897.903|||||F||1|19980827175800||123
6R|17|^^^Na+_M1^M|66.348|||||F||1|19980827175800||123
7R|18|^^^pH_SL^M|10.584|||||F||1|19980827175800||123
0R|19|^^^PCO2_SL^M|10.389|||||F||1|19980827175800||123
1R|20|^^^PO2_SL^M|-6.731|||||F||1|19980827175800||123
```

```
2R|21|^^^Hb_SL^M|10.000|||||F||1|19980827175800||123
3R|22|^^^Hct_SL^M|24.293|||||F||1|19980827175800||123
4R|23|^^^Na+_SL^M|8.863|||||F||1|19980827175800||123
5R|24|^^^S1_SM^M|201.127|||||F||1|19980827175800||123
6R|25|^^^S2_SM^M|170.187|||||F||1|19980827175800||123
7R|26|^^^S1_M1^M|200.144|||||F||1|19980827175800||123
0R|27|^^^S2_M1^M|169.418|||||F||1|19980827175800||123
1R|28|^^^S1_SL^M|0.770|||||F||1|19980827175800||123
2R|29|^^^S2_SL^M|1.104|||||F||1|19980827175800||123
3L|1|N
```

7.2.3 pHOx ABG Calibration

```
1H|\^&|||NOVA^pHOx^I00.53^123|||||||1|19980827172200
2P|1||
3O|1|||||||||||||Cal||||||||||F
4R|1|^^^pH_M1^M|28.478|||N||F|||19980827172200||123
5R|2|^^^pH_M2^M|25.114|||N||F|||19980827172200||123
6R|3|^^^pH_M3^M|29.803|||N||F|||19980827172200||123
7R|4|^^^pH_M4^M|63.084|||N||F|||19980827172200||123
0R|5|^^^PCO2_M1^M|88.510|||N||F|||19980827172200||123
1R|6|^^^PCO2_M2^M|101.932|||N||F|||19980827172200||123
2R|7|^^^PO2_M1^M|-115.677|||N||F|||19980827172200||123
3R|8|^^^PO2_M2^M||||N||F|||19980827172200||123
4R|9|^^^PO2_M3^M|-100.099|||N||F|||19980827172200||123
5R|10|^^^Hct_M1^M|1897.903|||N||F|||19980827172200||123
6R|11|^^^Hct_M2^M||||N||F|||19980827172200||123
7R|12|^^^Hct_M4^M|877.612|||N||F|||19980827172200||123
0R|13|^^^Na+_M1^M|64.789|||N||F|||19980827172200||123
1R|14|^^^Na+_M2^M||||N||F|||19980827172200||123
2R|15|^^^Na+_M4^M|49.057|||N||F|||19980827172200||123
3R|16|^^^pH_SL^M|10.584|||N||F|||19980827172200||123
4R|17|^^^PCO2_SL^M|10.389|||N||F|||19980827172200||123
5R|18|^^^PO2_SL^M|-6.731|||N||F|||19980827172200||123
6R|19|^^^Hb_SL^M|0.000|||A||F|||19980827172200||123
7R|20|^^^Hct_SL^M|24.293|||N||F|||19980827172200||123
0R|21|^^^Na+_SL^M|8.863|||N||F|||19980827172200||123
1L|1|N
```

7.2.4 pHOx SO2% Calibration

```
1H|\^&|||NOVA^pHOx^I00.53^123||||||||1|19980827173400
2P|1||
3O|1|||||||||||||Cal||||||||||F
4R|1|^^^S1_M1^M|319.258|||N||F|||19980827173400||123
5R|2|^^^S2_M1^M|305.213|||N||F|||19980827173400||123
6R|3|^^^S1_M2^M|665.084|||N||F|||19980827173400||123
7R|4|^^^S2_M2^M|275.745|||N||F|||19980827173400||123
0R|5|^^^S1_M3^M|-13.953|||N||F|||19980827173400||123
1R|6|^^^S2_M3^M|-16.503|||N||F|||19980827173400||123
2R|7|^^^S1_M4^M|200.954|||N||F|||19980827173400||123
3R|8|^^^S2_M4^M|170.514|||N||F|||19980827173400||123
4R|9|^^^S1_SL^M|0.770|||N||F|||19980827173400||123
5R|10|^^^S2_SL^M|1.104|||N||F|||19980827173400||123
6L|1|N
```

7.2.5 Combined Patient Sample

```
1H|\ ^&|||NOVA^pHOx^i04.07^6||||||||1|20011107100100
2P|1||123456789012345||
3O|1|1234567890|106||||||||||||Arterial||||||||||F
4C|1|I|55  Hct/Air Det Dependenc|I
5R|1|^^^pH^M|7.616|||||F||123456789012|20011107095800||6
6R|2|^^^PCO2^M|22.5|mmHg||||F||123456789012|20011107095800||6
7R|3|^^^PO2^M|147.0|mmHg||||F||123456789012|20011107095800||6
0R|4|^^^Hb^M||g/dL||||F||123456789012|20011107095800||6
1R|5|^^^Hct^M^D|43|%||||F||123456789012|20011107095800||6
2R|6|^^^SO2%^M||||||F||123456789012|20011107095800||6
3R|7|^^^pHTC^T|7.616|||||F||123456789012|20011107095800||6
4R|8|^^^PCO2TC^T|22.5|mmHg||||F||123456789012|20011107095800||6
5R|9|^^^PO2TC^T|147.0|mmHg||||F||123456789012|20011107095800||6
6R|10|^^^HCO3-^C|23.1|mmol/L||||F||123456789012|20011107095800||6
7R|11|^^^BE-b^C|?4.0|mmol/L||||F||123456789012|20011107095800||6
0R|12|^^^BE-ecf^C|1.6|mmol/L||||F||123456789012|20011107095800||6
1R|13|^^^TCO2^C|23.8|mmol/L||||F||123456789012|20011107095800||6
2R|14|^^^SBC^C|?31.8|mmol/L||||F||123456789012|20011107095800||6
3R|15|^^^A^C|124.4|mmHg||||F||123456789012|20011107095800||6
4R|16|^^^a/A^C|1.2|||||F||123456789012|20011107095800||6
5R|17|^^^O2Ct^C|?48.1|mL/dL||||F||123456789012|20011107095800||6
6R|18|^^^O2CAP^C|?18.3|mL/dL||||F||123456789012|20011107095800||6
7R|19|^^^CcO2^C|?0.1|mL/dL||||F||123456789012|20011107095800||6
```

```
0R|20|^^^CaO2^C|?-7.0|mL/dL||||F||123456789012|20011107095800||6
1R|21|^^^THb^M|?13.2|g/dL||||F||123456789012|20011107095800||21
2R|22|^^^HHb^M|?25.0|%||||F||123456789012|20011107095800||21
3R|23|^^^O2Hb^M|?-40.6|%||||F||123456789012|20011107095800||21
4R|24|^^^SO2%^M|?259.9|||||F||123456789012|20011107095800||21
5R|25|^^^COHb^M|?99.5|%||||F||123456789012|20011107095800||21
6R|26|^^^MetHb^M|?16.1|%||||F||123456789012|20011107095800||21
7R|27|^^^O2Ct^M||mL/dL||<||F||123456789012|20011107095800||21
0R|28|^^^O2CAP^M||mL/dL||<||F||123456789012|20011107095800||21
1R|29|^^^TempP^D|37.0|deg C||||F||123456789012|20011107095800||6
2R|30|^^^BP^M|755.1|mmHg||||F||123456789012|20011107095800||6
3R|31|^^^TempM^M|37.0|deg C||||F||123456789012|20011107095800||6
4R|32|^^^FIO2^D|20.9|%||||F||123456789012|20011107095800||6
5R|33|^^^tidal_volume^E|20.0|||||F||123456789012|20011107095800||6
6R|34|^^^peep_cpap^E|50.0|||||F||123456789012|20011107095800||6
7R|35|^^^pH_SM^M|84.22|||||F||123456789012|20011107095800||6
0R|36|^^^PCO2_SM^M|118.21|||||F||123456789012|20011107095800||6
1R|37|^^^PO2_SM^M|-88.61|||||F||123456789012|20011107095800||6
2R|38|^^^Hct_SM^M|880.69|||||F||123456789012|20011107095800||6
3R|39|^^^pH_M1^M|93.97|||||F||123456789012|20011107095800||6
4R|40|^^^PCO2_M1^M|124.37|||||F||123456789012|20011107095800||6
5R|41|^^^PO2_M1^M|-104.21|||||F||123456789012|20011107095800||6
6R|42|^^^Hct_M1^M|1926.86|||||F||123456789012|20011107095800||6
7R|43|^^^pH_SL^M|10.50|||||F||123456789012|20011107095800||6
0R|44|^^^PCO2_SL^M|10.18|||||F||123456789012|20011107095800||6
1R|45|^^^PO2_SL^M|-6.27|||||F||123456789012|20011107095800||6
2R|46|^^^Hb_SL^M|10.00|||||F||123456789012|20011107095800||6
3R|47|^^^Hct_SL^M|24.16|||||F||123456789012|20011107095800||6
4R|48|^^^S1_SM^M|275.06|||||F||123456789012|20011107095800||6
5R|49|^^^S2_SM^M|521.26|||||F||123456789012|20011107095800||6
6R|50|^^^S1_M1^M|60.38|||||F||123456789012|20011107095800||6
7R|51|^^^S2_M1^M|281.84|||||F||123456789012|20011107095800||6
0R|52|^^^S1_SL^M|9.24|||||F||123456789012|20011107095800||6
1R|53|^^^S2_SL^M|10.03|||||F||123456789012|20011107095800||6
2R|54|^^^puncture_site^E|Femoral Artery|||||F||123456789012|20011107095800||6
3R|55|^^^mode_of_therapy^E|CPAP|||||F||123456789012|20011107095800||6
4R|56|^^^ventilator_rate^E|.2|||||F||123456789012|20011107095800||6
5L|1|N
```

7.2.6 pHOx Only QC Sample

```
1H|\^&|||NOVA^pHOx^I00.53^123|||||||1|19980827180000
2P|1||123456
3O|1|QC4 Level 1 External|0|||||||||||Control|||||||||F
4C|1|I|35  SO2% Dependency|I
5C|2|I|45  Hb Dependency|I
6R|1|^^^H+^M|70.479|nmol/L||||F||1|19980827175800||123
7R|2|^^^PCO2^M|59.8|mmHg||||F||1|19980827175800||123
0R|3|^^^PO2^M|62.3|mmHg||||F||1|19980827175800||123
1R|4|^^^Hb^M||g/dL||||F||1|19980827175800||123
2R|5|^^^Hct^M||%||<||F||1|19980827175800||123
3R|6|^^^SO2%^M||||||F||1|19980827175800||123
4R|7|^^^Na+^M||mmol/L||||F||1|19980827175800||123
5R|8|^^^pH_SM^M|43.290|||||F||1|19980827175800||123
6R|9|^^^PCO2_SM^M|102.995|||||F||1|19980827175800||123
7R|10|^^^PO2_SM^M|-42.850|||||F||1|19980827175800||123
0R|11|^^^Hct_SM^M|2243.885|||||F||1|19980827175800||123
1R|12|^^^Na+_SM^M||||||F||1|19980827175800||123
2R|13|^^^pH_M1^M|28.478|||||F||1|19980827175800||123
3R|14|^^^PCO2_M1^M|88.510|||||F||1|19980827175800||123
4R|15|^^^PO2_M1^M|-115.677|||||F||1|19980827175800||123
5R|16|^^^Hct_M1^M|1897.903|||||F||1|19980827175800||123
6R|17|^^^Na+_M1^M|66.348|||||F||1|19980827175800||123
7R|18|^^^pH_SL^M|10.584|||||F||1|19980827175800||123
0R|19|^^^PCO2_SL^M|10.389|||||F||1|19980827175800||123
1R|20|^^^PO2_SL^M|-6.731|||||F||1|19980827175800||123
2R|21|^^^Hb_SL^M|10.000|||||F||1|19980827175800||123
3R|22|^^^Hct_SL^M|24.293|||||F||1|19980827175800||123
4R|23|^^^Na+_SL^M|8.863|||||F||1|19980827175800||123
5R|24|^^^S1_SM^M|201.127|||||F||1|19980827175800||123
6R|25|^^^S2_SM^M|170.187|||||F||1|19980827175800||123
7R|26|^^^S1_M1^M|200.144|||||F||1|19980827175800||123
0R|27|^^^S2_M1^M|169.418|||||F||1|19980827175800||123
1R|28|^^^S1_SL^M|0.770|||||F||1|19980827175800||123
2R|29|^^^S2_SL^M|1.104|||||F||1|19980827175800||123
3L|1|N
```

A Appendix

Appendix A includes analyzer specifications, solutions and reagents, consumable lists, reference information, and warranty for the Stat Profile pHOx Analyzer.

A.1 Stat Profile pHOx Specifications*

Measurement Range:	pH	6.500 - 8.000	H^+ 316.23 - 10.00 nmol/L	
	PCO_2	3.0 - 200 mmHg	0.4 - 26.7 kPa	
	PO_2	0 - 800 mmHg	0.0 - 106.7 kPa	
	SO_2	30.0 - 100 %	0.0 - 1.00	
	Hct	12% - 70%		
	Hb	4.0 - 24.0 g/dL	40.0 - 240 g/L	2.5-14.9 mmol/L
	BarP	400.0 - 800.0 mmHg	53.3 - 106.7 kPa	15.7- 31.5 inHg

Calculated Result Resolution:	HCO_3	0.1 mmol/L		
	TCO_2	0.1 mmol/L		
	Beecf	0.1 mmol/L		
	Beb	0.1 mmol/L		
	SBC	0.1 mmol/L		
	O_2Ct	0.1 mL/dL		
	P50	0.1 mmHg	0.1 kPa	
With entered FiO_2:	A	0.1 mmHg	0.1 kPa	
	A-aDO_2	0.1 mmHg	0.1 kPa	
	a/A	0.1		
	PO_2/FiO_2	0.1 mmHg	0.1 kPa	
With CO-OX inputs:	MetHb	0.1 %	0.001	
	COHb	0.1 %	0.001	
	HHb	0.1 %	0.001	
	O_2Hb	0.1 %	0.001	
	O_2Cap	0.1 mL/dL	0.01 mL/L	
	O_2Ct	0.1 mL/dL	0.01 mL/L	
Combined:	CcO_2	0.1 mL/dL		
	CaO_2	0.1 mL/dL		
	CvO_2	0.1 mL/dL		
	a-vDO_2	0.1 mmHg	0.1 kPa	
	P50	0.1 mmHg	0.1 kPa	

NOTE: *If the calculated result of* ***$AaDO_2$*** *is less than or equal to zero, the test and its result will not be displayed.*

*Specifications are subject to change

Acceptable Samples:	Whole Blood (heparinized)
Measuring Technology:	Ion Selective Electrodes (Na^+, pH, PCO_2) Amperometry (PO_2) Conductivity (Hematocrit/Hemoglobin) Reflectance Photometry (Oxygen Saturation/Hemoglobin)

Analysis Rate:

Stat Analysis Time	Throughput Time
45 seconds	60 seconds

Sample Volume:	45 microliters whole blood micro sample for blood gases 70 microliters whole blood sample size for full panel
Barometer:	400 - 800 ±1 mmHg, accurate to 1.5 mmHg

Slope Limits:

pH	9.1 - 11.6
PO_2	-15.0 - (-1.6)
PCO_2	7.9 - 12.6
Hct	12.0 - 50.0
Na^+	8.3 - 12.0
SO_2	6.9 - 18.2

Slope and Offset Limits:

	Slope	Offset
pH	N/A	lower -0.1 upper 0.1
PCO_2	lower 0.80 upper 1.20	lower -10.0 upper 10.0
PO_2	lower 0.90 upper 1.1	lower -20.0 upper 20.0
SO_2	lower 0.90 upper 1.1	N/A
Hct	lower 0.80 upper 1.20	lower -10.0 upper 10.0
Hb	lower 0.9 upper 1.1	lower -2.0 upper 2.0

*Specifications are subject to change.

Analytical Specifications for Imprecision

Analyte	Within-run Precision n=20		Day-to-Day Precision n=20	
	Whichever is Greater		Whichever is Greater	
	CV%	SD	CV%	SD
pH		0.005		0.013
PCO_2	3.0	1.0 (mmHg)	5.0	2.0 (mmHg)
PO_2	3.0	1.5 (mmHg)	5.0	3.0 (mmHg)
Hct		1.0 Hct%		1.0 Hct%
Hb	2.5%	0.3 g/dL		
SO_2		1.0 SO_2%		1.5 SO_2%

Stat Profile pHOx vs Ultra E Method Comparison

Analyte	Mode	Number of Samples N	Correlation Coefficient R	Range	Reference Instrument
pH	Blood	52	0.997	6.88 - 7.44	STAT Ultra E
PCO_2	Blood	56	0.998	28 - 112 mmHg	STAT Ultra E
PO_2	Blood	56	0.999	18 - 414 mmHg	STAT Ultra E
Hct	Blood	50	0.986	16% - 68%	STAT Ultra E
Hb	Blood	40	0.995	6 - 21 g/dL	STAT Ultra E
SO_2	Blood	50	0.998	32.6% - 99.0%	STAT Ultra E

*Specifications are subject to change.

Electrical Compliance:	Meets IEC 1010, UL, and CSA standards	
Temperature Thermostatting:	37 °C ± 0.1 °C	
Dimensions:	Height:	15.0 in (38.1 cm)
	Width:	12.0 in (30.5 cm)
	Depth:	15.0 in (38.1 cm)
Weight:	18 lb (8.19 kg) without reagent pack 23 lb (10.45 kg) with full reagent pack	
Power:	100-120; 220-240 VAC, 50/60 Hz, 130W	
Environmental:	Indoor use at temperature between 15°C and 30°C (59°F and 86°C); altitude up to 2000 meters; Relative Humidity of 0-85% (noncondensing)	

Lifting the Analyzer:

1. One person is needed to lift the analyzer.

CAUTION: *Never use the control panel or doors (open or closed) to assist you in lifting the analyzer. They cannot support the weight of the analyzer.*

2. From the front of the analyzer, place your hands under each side of the analyzer.
3. Lift the analyzer. Remember to bend your knees and lift with your legs and not your back.
4. Place the analyzer onto a clean and flat surface.

A.2 Reagents and Solutions

This section covers the reagents and solutions required for proper operation and maintenance of the Stat Profile pHOx Analyzer.

A.2.1 Reagents and Solutions

Reagents and solutions are as follows:

1. Reagent Pack: PN 20807
2. pH Electrode Conditioning Solution: PN 23397
3. Preheater Cleaning Agent: PN 11802

4. Nova Stat Profile pHOx SO_2 Calibrators PN 22771:
   - External Calibrator Level 1 - SO_2
   - External Calibrator Level 2 - SO_2

5. Nova Stat Profile pHOx Controls:
   - Level 1 - Acidosis, with low pH, high PCO_2, low PO_2, low SO_2, & low normal Hct & Hb: PN 22760
   - Level 2 - Normal, with normal pH, PCO_2, and PO_2: PN 22761
   - Level 3 - Alkalosis, with high pH, low PCO_2, high PO_2, SO_2, and normal high Hct & Hb: PN 22762
   - Multi Pack: PN 22763

6. Auto-cartridge QC (Internal): PN 23930, PN 23931, PN 23932, PN 23933

Nova will not be responsible for any of its warranties on sensors, electrodes, tubing, probes, or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Some reagent formulations not manufactured by Nova contain acids, concentrated salt solutions, and artificial preservatives which have been shown to cause problems such as shortened sensor/electrode life, sensor/electrode membrane damage, sensor/electrode drift, erratic analytical results, and unacceptable instrument performance.

> ***NOTE:*** *Refer to the Nova Stat Profile Control insert for storage requirements for these controls. Store all other Nova Stat Profile reagents, standards, and solutions at 15 to 30° C.*

A.2.2 Reagent Pack

The concentrations of the internal standards* are printed on the reagent pack. In addition to the reagents and solutions, the reagent pack has a self-contained waste bag for safe disposal of waste.

A.2.3 Verifying the Analyzer's Performance

Nova Biomedical recommends that each laboratory performs the following minimum QC procedures on each analyzer:

- Stat Profile pHOx Blood Gas/SO_2/Hct/Hb Controls Levels 1, 2, 3
  - During each 8 hours of testing, analyze one level of Stat Profile pHOx Control.
  - Analyze all 3 levels during each day of operation.

CAUTION: *The sensor performance of the analyzer may be affected by use of controls other than Nova Stat Profile pHOx Controls. Contact Nova Biomedical for additional information.*

A.2.3.1 Nova Stat Profile pHOx Controls Levels 1, 2, 3: Quality Control

The pHOx Analyzer can perform internal or external Quality Control. The internal controls are analyzed at the programed times inputted into the QC Setup. The control levels 1, 2, and 3 are contained in the Control Pack. The in control results are printed only if the Analysis Print Mode is ON. If a result is out of range (not in control), up or down arrows will print next to the result, and the Exceed Limits screen is displayed.

To run internal controls manually proceed as follows:

1. From the Ready screen, press QC (soft key)
2. Select Analyze QC with the arrow keys then press Enter
3. Press Next Control (soft key) until QC Select Internal L1 screen is displayed: this is Internal Control Level 1.
4. Press Analyze (soft key): QC Results Internal 1 screen is displayed. There are 2 results screens. Press Next Page (soft key) to view second screen.
5. To print the results of QC Level 1, press Print (soft key).
6. Repeat steps 1 - 5 to run internal QC Level 2 and again to run internal QC Level 3.

To run external controls, use the Nova Stat Profile pHOx Controls formulated as Levels 1, 2, and 3:

Level 1 - Acidosis, with low pH, high PCO_2, low PO_2, low SO_2, & low normal Hct & Hb

Level 2 - Normal, with normal pH, PCO_2, and PO_2

Level 3 - Alkalosis, with high pH, low PCO_2, high PO_2, SO_2, and normal high Hct & Hb

The ampules must be at 25° C for at least 24 hours before opening.

> ***CAUTION:*** *The sensor performance of the analyzer may be affected by use of controls other than Nova Stat Profile pHOx Controls.*

Analyze the Nova Stat Profile pHOx Controls Levels 1, 2, 3, as follows:

1. Before opening, shake the ampule for about 10 seconds.
2. Protect the fingers with tissue or gloves. Snap open the ampule.

   > ***CAUTION:*** *Analyze the liquid within 30 SECONDS of opening to prevent contamination with room air and alteration of stated values.*

3. Press QC, select level, present the control, press Continue (soft key) to initiate aspiration, and press Analyze (soft key) to present sample to sensors.
4. Compare the results with those listed in the assay data sheet included with the controls.

A.3 Reference Values

Each laboratory should establish and maintain its own reference values. The values given here should be used **only as a guide.**

Table D.1 Reference Values[1,2]

Test	Value
pH	7.35 - 7.45
PCO_2	35 - 45 mmHg
HCO_3^-	21 - 28 mmol/L
Base Excess (Blood)	(-2)-(+3) mmol/L
PO_2	83 - 108 mmHg
SO_2 (arterial whole blood)	95 - 98%
Hematocrit (Hct) (Male) (Female)	 39 - 49% 35 - 45%
Hemoglobin (Hb) (Male) (Female)	 13.2 - 17.3 g/dL 11.7 - 15.5 g/dL

References:

1. Statland, Bernard. 1987. *Clinical Decisions Levels for Lab Tests*, Medical Economics Books.

2. Tietz, Norbert W., ed. 1994. *Textbook of Clinical Chemistry*, W.B. Saunders Co., Philadelphia, Penn.

A.4 Ordering Information

Supplies and parts for the Stat Profile pHOx Analyzer are available from Nova Biomedical.

DESCRIPTION	Part #
Maintenance Log	22362
Reference Manual	22363
Air Detector (Sample)	21513
Bar Code Scanner (optional)	23591
Blank Sensor (Electrode)	22507
Clot Removal Tool	18431
Electrode Conditioning Holder	09458
Keyboard Kit (External)	33963
Linearity Solution Set G, L1 (Hematocrit/Hemoglobin)	24877
Linearity Solution Set G, L2 (Hematocrit/Hemoglobin)	24878
Line Power Cord	01498
PCO_2 Sensor and Washer	21524
PCO_2 Membrane Kit	25048
pH Sensor Conditioning Solution	23397
pH Sensor	21522
PO_2 Sensor	21521
PO_2 Membrane Kit	21795
Preheater Deproteinizing Solution	12704
Printer Paper (5 Rolls)	23298
Probe Cleaning Kit	02702
Reference Electrode	21520
Reference Line	21497
Sample Probe Assembly	21519
Sensor Module	21494
Shaft for Paper Roll	22816
SO_2 Sensor	21512
Sodium Sensor	21523

Ordering Information (cont'd)

DESCRIPTION	Part #
Stat Profile pHOx Auto-Cartridge QC Econo	23930
Stat Profile pHOx 1 Auto-Cartridge QC	23931
Stat Profile pHOx 2 Auto-Cartridge QC	23932
Stat Profile pHOx 3 Auto-Cartridge QC	23933
Stat Profile pHOx Control Multipack	22763
Stat Profile pHOx Reagent Pack A	23935
Stat Profile pHOx Reagent Pack B	23937
Stat Profile pHOx Reagent Pack C	23936
Stat Profile pHOx Reagent Pack D	23934
Stat Profile pHOx SO2 Calibrators Level 1 and 2	22771
Waste Line	21926
W/R Pump Tube assembly	23023

A.5 Shutdown Procedure

If the analyzer is to be turned off for more than 24 hours, flush the tubing harness first with distilled water then with air. Use the Flush Fixture (PN 24327) to perform this procedure.

> ***NOTE:*** *If the analyzer is to be shutdown for more than 1 week, remove the sensors and rinse and dry the flow cell.*

1. Remove the Reagent Pack from the analyzer.
2. Install the Flush Fixture into the analyzer in the same way as the Reagent Pack.
3. Place the W-line of the fixture into an empty container.
4. Place the other tubing ends into a beaker of distilled water.
5. From the Ready/Not Ready screen, press Menu (soft key).
6. Select Flowpath Maintenance and press Enter.
7. Press Purge (soft key).
8. When the cycle ends, take all the tubings out of the distilled water. Leave the W-line in its container.
9. Repeat the purge with air.
10. When this cycle is completed, remove the flush fixture.
11. Relax the pump tubing by removing one of the mounting blocks from its bracket.
12. The pHOx Analyzer is now ready to be powered off for extended time.

A.5 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. **All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure.** Nova Biomedical reserves the right to change,

alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. All requests for service outside Nova's principal hours of operation will be rendered at the prevailing weekend/holiday rates after receipt of an authorized purchase order. Contact Nova for specific information.

The following exceptions apply:

1. The sodium sensor is warranted for one (1) month and the pH, PCO_2, PO_2, and reference electrodes are warranted for six (6) months from the date of installation, provided they are stored at room temperature and placed into service prior to the use before date on the packaging. In the event that a sensor/electrode does not meet that use life, then Nova Biomedical will replace that sensor/electrode at no charge under this warranty. This warranty is invalid under the conditions specified after item 3.
2. Consumable items, including the reagent pack, calibration gases, replaceable membranes, tubing and tubing harnesses, electrolyte solutions, external standards, and septum assemblies are warranted to be free of defects at time of installation. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing. This warranty is invalid under the conditions specified after item 3.
3. Freight is paid by the customer.

The above warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows:
   Nova Biomedical will not be responsible for any warranties on sensors/electrodes, tubing, probes, septa, or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as shortened sensor/electrode and septa life, sensor/electrode membrane damage, sensor/electrode drift, erratic analytical results, and inaccurate instrument performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

B Theory

This section explains instrument theory of the Stat Profile pHOx Analyzer.

B.1 Sensor Calibration

B.1.1 Two-Point Calibration

The analyzer uses a 2-point calibration to set sensor slope and verify sensor performance. The reagent pack and the external calibrators (ampules) contain the standards which are used for this purpose. Calibration can be initiated manually by pressing CALIBRATE and is also initiated automatically by the system at intervals of 2, 4, or 6 hours depending on user setup. The External Two Standard Hb, SO_2% Calibration sequence is not initiated automatically.

B.1.2 One-Point Calibration

Sensor drift is the slow variation in sensor response over time. The determination of the activity for an unknown sample is dependent on both the sensor potential generated by the unknown and that generated by the standard. The analyzer uses a 1-point calibration to monitor and minimize the effect of the sensor drift on the analytical results. If analyzer is in Mode A, a 1-point calibration occurs at 30 minute intervals and is independent of the sample cycle. If analyzer is in Mode B, the 1-point calibration occurs with every analysis.
A drift error code is displayed when sensor drift is beyond the drift limits

B.2 Parameter Definitions

B.2.1 pH Sensor

Definition of pH

The pH of an unknown sample is calculated using the following equation:

$$pH_x = pH_{std\ C} + \frac{E_{Std\ C} - E_x}{Slope} \qquad \text{Equation 1}$$

$$\text{where Slope} = \frac{E_{std\ C} - E_x}{pH_{std\ C} - pH_{std\ D}} \qquad \text{Equation 2}$$

Principle of pH Measurement

pH is measured using a hydrogen ion selective glass membrane. One side of the glass is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions. This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure, then, of the pH of the unknown solution.

B.2.2 Partial Pressure of Carbon Dioxide (PCO_2)

Definition of PCO_2

The partial pressure (tension) of carbon dioxide in solution is defined as the partial pressure of carbon dioxide in the gas phase in equilibrium with the blood.

Principle of PCO_2 Measurement

PCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a gas permeable membrane mounted on a combination measuring/reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity.

$$CO_2 + H_2O \Leftrightarrow H_2CO_3 \Leftrightarrow H^+ + \left[HCO_3^-\right] \qquad \text{Equation 3}$$

The electrolyte solution behind the membrane is in contact with a glass hydrogen ion selective sensor. The change in hydrogen ion activity in the electrolyte solution produces a potential which is measured against the internal filling solution. This change in potential is measured against the constant potential of the reference electrode half cell and is logarithmically related to the PCO_2 of the unknown sample.

B.2.3 Partial Pressure of Oxygen (PO_2)

Definition of PO_2

The partial pressure (tension) of oxygen in solution is defined as the partial pressure of oxygen in the gas phase in equilibrium with the blood. PO_2 provides an indication of the availability of oxygen in inspired air.

Principle of PO_2 Measurement

PO_2 is measured amperometrically by the generation of a current at the sensor surface. As oxygen diffuses through a gas permeable membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the sensor and is directly proportional to the partial pressure of oxygen.

B.2.4 Hematocrit

Hematocrit is defined as the percentage of red blood cells to the total blood volume and can be obtained by measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value. Next, the hematocrit value obtained is corrected for the concentration of the sodium ion.

B.2.5 Hemoglobin (Measured)

Hemoglobin is measured by combining a conductivity measurement and a photometric measurement. The combination provides a measure of the hemoglobin concentration. It is refined by the SO_2 measurement that adjusts the hemoglobin concentration for the effects of red cell morphology changes with saturation and for the concomitant effects on the relationship between the sample conductivity and the packed volume of red cells in the blood sample.

B.2.6 SO_2 % Concentration

Definition of SO_2

Oxygen saturation, SO_2%, represents the percent of hemoglobin bound to oxygen, expressed as a fraction of the amount of hemoglobin capable of binding to oxygen (oxyhemoglobin plus deoxyhemoglobin). As the level of SO_2% changes within a blood sample, the color of the whole blood changes.

Principle of SO_2 Measurement

On the Stat Profile pHOx analyzer, a reflectance photometry system is used to measure the color of the whole blood to determine the level of oxygen saturation. Using a multiple branch bundle of optical fibers, the whole blood sample is illuminated by multiple wavelengths of light. A portion of each wavelength of light is reflected onto one of the optical fiber bundles and in turn onto a photo detector. By relating the signal observed to those of known standards, the color of the blood sample is measured, and the level of oxygen saturation is determined.

B.3 Calculated Values

The analyzer's microcomputer uses the measured results to calculate other clinically valuable parameters. This section outlines the equations used to calculate these values.

B.3.1 Temperature Correction for Measured Values*

The Stat Profile Ultra analyzer allows you to enter the patient temperature when this differs from 37 °C, as for example in patients having surgery under hypothermia. The pH, PCO_2, and PO_2 sample values, at the patient's actual temperature, are then calculated as follows:

$$pH_{(corrected)} = pH + [- 0.0147 + 0.0065\ (7.400 - pH)](T - 37) \qquad \text{Equation 4}$$

$$PCO_{2\ (corrected)} = PCO2 \times e^{\ (0.04375(T - 37))} \qquad \text{Equation 5}$$

$$PO_{2(corrected)} = PO_2 \times 10^{U} \qquad \text{Equation 6}$$

where $U = \left(\left[\frac{\left(5.49 \times 10^{-11}\right)Y + 0.071}{\left(9.72 \times 10^{-9}\right)Y + 2.30} \right] \times (T - 37) \right)$ and $Y = e\left[3.88 \times \ln\left(PO_2\right)\right]$

*The equations are from NCCLS standards[2].

B.3.2 Calculated Parameters

Calculated Bicarbonate Concentration [HCO_3^-]*

Bicarbonate Concentration (mmol/L) is calculated using the Henderson-Hasselbalch equation:

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha(PCO_2)} \qquad \text{Equation 7}$$

where pH and PCO_2 are measured.

pK = 6.091

α = 0.0307 = solubility coefficient of CO_2 in plasma at 37 °C

Rearranging Equation 7 gives:

$$\text{Log}_{10}[HCO_3^-] = pH + \log_{10} PCO_2 - 7.604 \qquad \text{Equation 8}$$

*The equations are from NCCLS standards[2].

Total Carbon Dioxide Content (TCO_2)*

TCO_2 (mmol/L) includes both dissolved carbon dioxide and [HCO_3^-] and is calculated as follows:

$$TCO_2 = [HCO_3^-] + \alpha(PCO_2) \qquad \text{Equation 9}$$

where PCO_2 is measured and [HCO_3^-] is calculated from Equation 8.

*The equations are from NCCLS standards[2].

Hemoglobin (Calculated)

The hemoglobin is calculated based on the following calculation:

$$\text{Hemoglobin g/dL} = \text{Measured Hematocrit} \div 3.0 \qquad \text{Equation 10}$$

NOTE: *The hemoglobin calculation is an estimation based on a normal mean corpuscular hemoglobin concentration of 33.3%. The Stat Profile pHOx hemoglobin estimation from samples with Red cell dyscrasia or hemoglobinopathies may vary significantly from hemoglobin measured by cyanmethemoglobin method.*

Base Excess of Blood (BE-B: sometimes called In Vitro Base Excess)*

Base excess of blood is defined as the concentration of titratable base needed to titrate blood to pH 7.40 at 37 °C while the PCO_2 is held constant at 40 mm Hg. Base excess of blood is calculated as follows:

$$BE\text{-}B = (1 - 0.014[Hb])\,([HCO_3^-] - 24 + (1.43[Hb] + 7.7)(pH - 7.4)) \qquad \text{Equation 11}$$

*The equations are from NCCLS standards[2].

Standard Bicarbonate Concentration (SBC)

The Standard Bicarbonate is defined as the bicarbonate concentration of the plasma of whole blood equilibrated to a PCO_2 of 40 mmHg at a temperature of 37 °C with the hemoglobin fully saturated with oxygen. Standard bicarbonate is calculated as follows:

$$SBC = 24.5 + 0.9Z + Z\,(\,Z - 8\,)(0.004 + 0.00025\,[Hb]) \qquad \text{Equation 12}$$

where $Z = [BE\text{-}B] - 0.19\,[Hb]\,((100 - SO_2)/100)$

[Hb] = The hemoglobin value which is measured, manually entered, or is the 14.3 g/dL default value

Base Excess Extracellular Fluid (BE-ECF)*

The Base Excess Extracellular fluid is a corrected form of the Base Excess Blood in which allowance has been made for the fact that blood is only approximately 37% of the extracellular fluid volume. Base excess is calculated as follows:

$$BE\text{-}ECF = [HCO_3^-] - 25 + 16.2\,(pH - 7.40) \qquad \text{Equation 13}$$

*The equations are from NCCLS standards[2].

Oxygen Content (O_2Ct)

Oxygen content is defined as the total amount of oxygen contained in a given volume of whole blood, including dissolved oxygen and oxygen bound to hemoglobin. It is expressed in milliliters of oxygen per 100 milliliters of blood (volume %) as calculated from the oxygen saturation and the hemoglobin concentration. Four moles of oxygen (22,393 mL/mol at standard temperature and pressure) can combine with 1 mole of hemoglobin (64,458 g/mol) so that oxygen capacity is equal to

$$\frac{4\,(22393)}{64458} = 1.39 \text{ mL of } O_2 \text{ per gram of Hb} \qquad \text{Equation 14}$$

therefore $$O_2Ct = (1.39\ [Hb])\left(\frac{SO_2}{100}\right) + (0.0031\ [PO_2])$$ Equation 15

where 0.0031 is the solubility coefficient of O_2.
On the analyzer, hemoglobin can be manually entered, calculated from the measured hematocrit, or occur as a default value.

Oxygen Saturation (O_2Sat)

Oxygen saturation is defined as the amount of oxyhemoglobin in blood expressed as a fraction of the total amount of hemoglobin able to bind oxygen. It is calculated as follows:

$$O_2Sat = \frac{[PO_2']^3 + 150\ [PO_2']}{[PO_2']^3 + 150\ [PO_2'] + 23400} \times 100$$ Equation 16

where

$$[PO_2'] = [PO_2] \times e\left[2.3026 \times \left(0.48\ (pH - 7.4) - 0.0013\left([HCO_3^-] - 25\right)\right)\right]$$

NOTE: *The equation for calculating oxygen saturation assumes a normal shape and position of the patient's oxygen dissociation curve.*

Alveolar Oxygen (A)

Alveolar Oxygen refers to the partial pressure of oxygen in alveolar gas. It is calculated as follows:

$$A = \frac{\%FIO_2}{100}(B.P. - 0.045T^2 + 0.84T - 16.5) - {}^{**}PCO_2\left(\frac{\%FIO_2}{100} + \left(\frac{1 - \frac{\%FIO_2}{100}}{0.8}\right)\right)$$

Equation 17

where T = patient temperature
B.P. = barometric pressure
$\%FIO_2$ = fraction inspired oxygen, as a percent

Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)

The arterial alveolar oxygen tension gradient is a useful index of gas exchange within the lungs and is defined as:

$$Aa\ DO_2 = A - {}^{**}PO_2 \qquad \text{Equation 18}$$

Arterial Alveolar Oxygen Tension Ratio (a/A)

The arterial alveolar oxygen tension ratio is useful to predict oxygen tension in alveolar gas and to provide an index of oxygenation which remains relatively stable when FIO_2 changes.

$$a/A = {}^{**}PO_2/A \qquad \text{Equation 19}$$

** Temperature corrected gas value

Arterial-Mixed Venous O_2 Content Difference ($a - \bar{v}DO_2$)

When the oxygenated blood from the lungs comes into contact with tissues, it releases oxygen and takes up carbon dioxide. The quantity of oxygen donated depends on 2 factors:

- The speed of blood flow
- The consumption by tissues

The first factor can be detected from the cardiac output, and the second depends on the metabolic rate of the patient.

The $a - \bar{v}DO_2$ is the measurement of the difference in oxygen content between the arterial blood and the mixed venous blood (the amount of oxygen donated to the tissues). This parameter is not an indication of the basic metabolism nor of the cardiac output. It is an nonspecific indication; even if, in some cases completely relaxed patients with a constant metabolic rate, it can be related to the cardiac output.

$$a - \bar{v}DO_2 = CaO_2 - C\bar{v}O_2 \qquad \text{Equation 20}$$

Physiologic Shunt (AV Shunt) Calculation ($\dot{Q}sp/\dot{Q}t$)

The estimation of shunt flow can be performed when both mixed venous and arterial blood samples are sent and they are analyzed on the pHOx interfaced to a Nova CO-Oximeter. The selection of syringe sample type analysis and the AV Shunt key is required. The instruments require analysis of the mixed venous sample first followed by the arterial sample on both the Stat Profile pHOx and Nova CO-Oximeter.

The Physiologic Shunt Calculation ($\dot{Q}sp/\dot{Q}t$) requires the calculation of the End Capillary Oxygen Content (Cc'O2), Arterial Oxygen Content (CaO_2) and Mixed Venous Oxygen Content ($C\bar{v}O_2$):

$$\dot{Q}sp/\dot{Q}t = \frac{Cc'O_2 - CaO_2}{Cc'O_2 - C\bar{v}O_2} \times 100 \qquad \text{Equation 21}$$

Where: $Cc'O_2 = 1.39 \times Hb \times 1.0$

$CaO_2 = 1.39 \times Hb \times SaO_2$ [from arterial sample]

$C\bar{v}O_2 = 1.39 \times Hb \times S\bar{v}O_2$ [from mixed venous ample]

*P*50 or PO_2 (0.5)*

The $P50$ is defined as the PO_2 of a sample at which the hemoglobin is 50% saturated with oxygen at pH 7.4, 37°C, and 40 mm Hg PCO_2 for SO_2 values between 40% and 80%.

$$\log P50_{(uncorrected)} = \log PO_2 - 0.37 \log\left(\frac{SO_2}{100 - SO_2}\right) \qquad \text{Equation 22}$$

$$\log P50_{(corrected)} = \log P50_{(uncorrected)} + 0.43(2.3)(\text{pH} - 7.4) - 0.05\left(\log\frac{PCO_2}{40}\right) - 0.031(2.3)(T - 37) \qquad \text{Equation 23}$$

* The equations are from Reference 4.

References:

1. Mohan, M.S. and Bates, R.G. 1977. *Blood pH, Gases and Electrolytes.* NBS Special Publication, 450. U.S. Government Printing Office.
2. National Committee for Clinical Laboratory Standards. 1982. *Tentative Standard for Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis.* NCCLS 2:10.
3. Williams, W.J., Beutler, E., Ersley, A.J., and Rundles, R.W. 1977. *Hematology.* 2nd ed. McGraw-Hill Co.
4. Tietz, Norbert W., ed. 1986. *Textbook of Clinical Chemistry.* W.B. Saunders Co. Philadelphia, Penn.

C Appendix

Appendix C includes all the information needed to install the pHOx Analyzer.

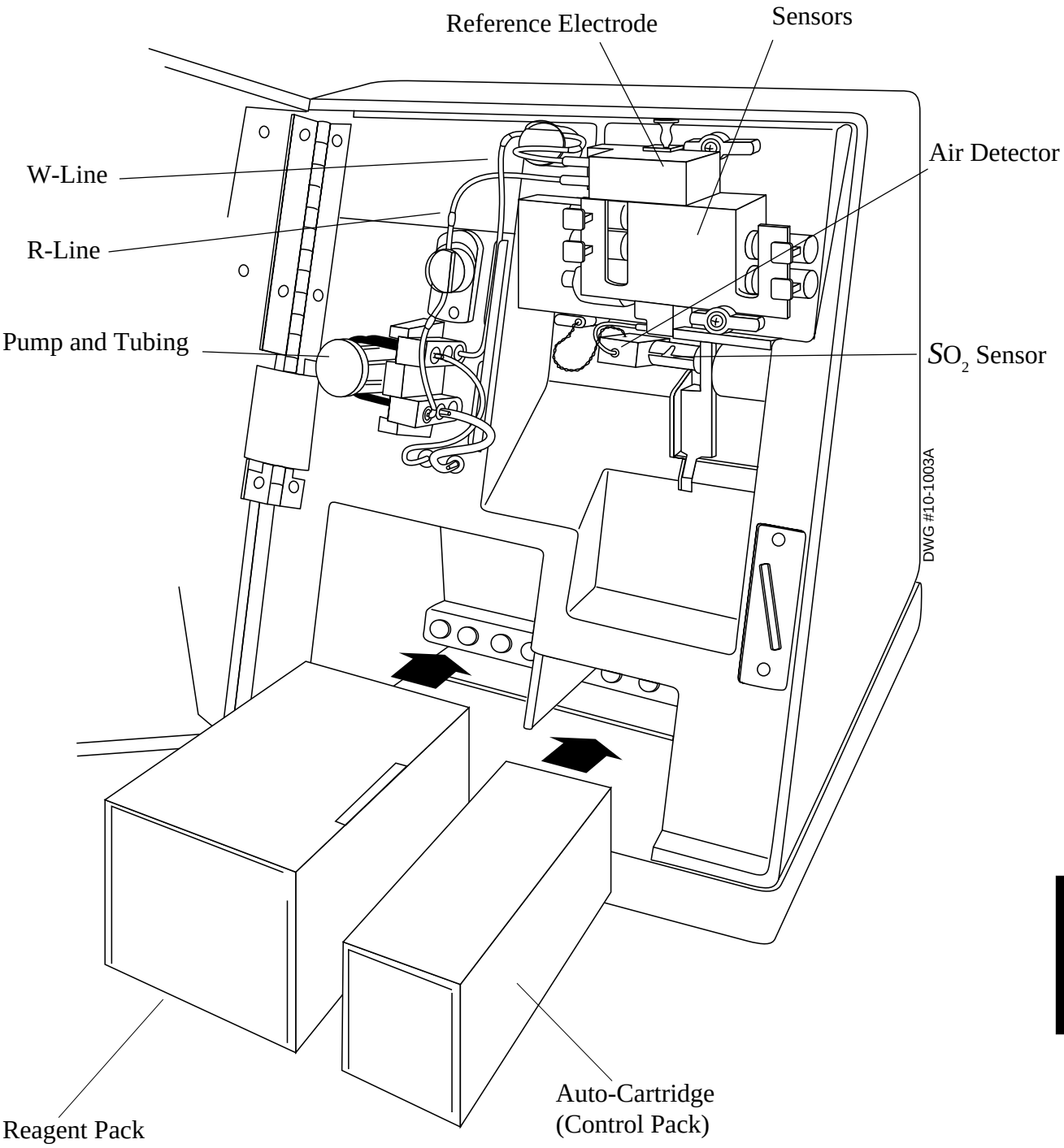


Figure C.1 pHOx Analyzer

C.1 pHOx Installation

1. Remove pHOx from box.
2. Install PCMCIA card in the slot on the bottom left corner of the back of the pHOx.
3. Verify the fuses are installed. (The fuse compartment is next to the power entry module on the back of the pHOx.)
4. Install the power cord into the power entry module on the back of the pHOx.

C.1.1 Printer Paper Installation

1. Open the printer cover.
2. Open the printer lever. Gently pull the lever to its opposing position.
3. Remove the paper holder.
4. Insert the paper holder into a new roll of paper. The loose end of the paper should feed from the bottom of the roll.
5. Install the roll of paper with holder into the support collars.
6. Push the paper through the back of the roller. Manually move the roller by using the knob next to the platen.
7. Center the paper and close the printer lever by pushing the lever back to its original position.
8. Feed paper through cover. Then close the printer cover.

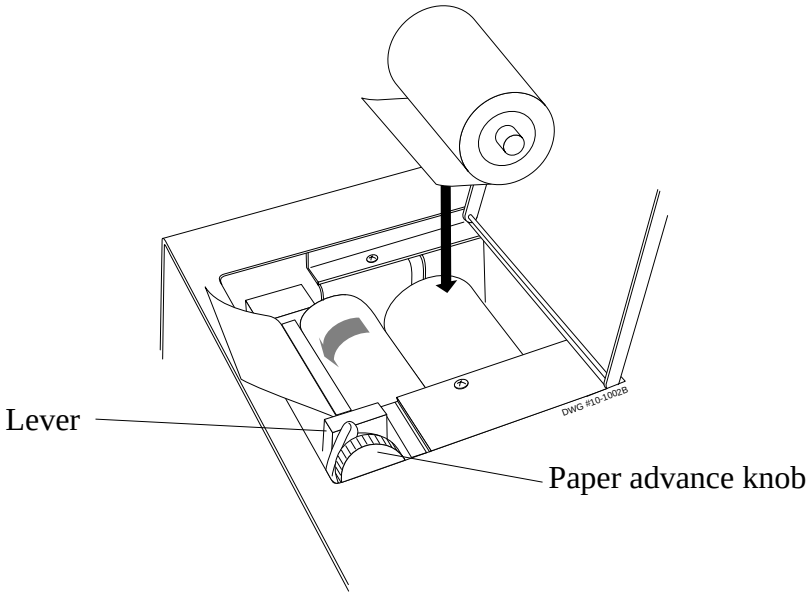


Figure C.2 Installing the Printer Paper

C.1.2 SO_2 Sensor Installation

1. Open the analytical compartment door (front of pHOx). Verify the Sensor module is installed.
2. Verify the SO_2 sensor is installed.
3. If not, remove the SO_2 sensor from its packaging.
4. Install the sensor by sliding it into the SO_2 position in the sensor module.
5. Tighten the lead screw.

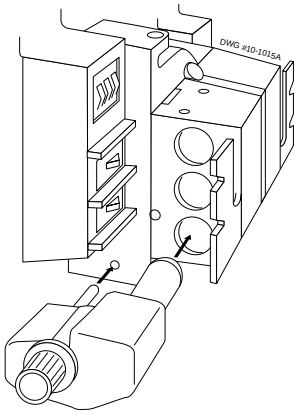


Figure C.3 Installing the SO_2 Sensor

C.1.3 Reference Electrode Installation

1. Remove the reference electrode from its packaging.
2. Place the new Reference Electrode on top of the sensor module; align the electrode sides with the backplate sides. Ensure the reference electrode connector is seated properly on the sensor module interconnect tubing.
3. Push down on the retaining screw.

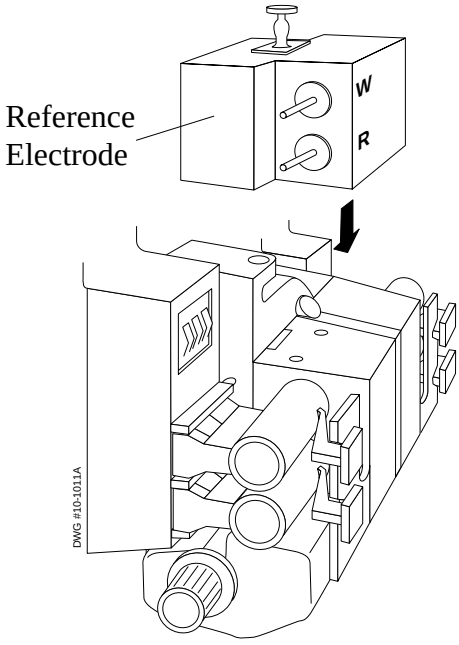


Figure C.4 Installing the Reference Electrode onto Sensor module

C.1.4 Pump Tubing Harness Installation

1. Remove the pump tubing from its packaging. Locate the half circle on one of the manifolds. This is the top manifold.
2. Slide the top pump tubing manifold into its slots. The top manifold's half circle should line up with the half circle on the slot.
3. Stretch the pump tubing around the pump and slide the bottom manifold into its slots.

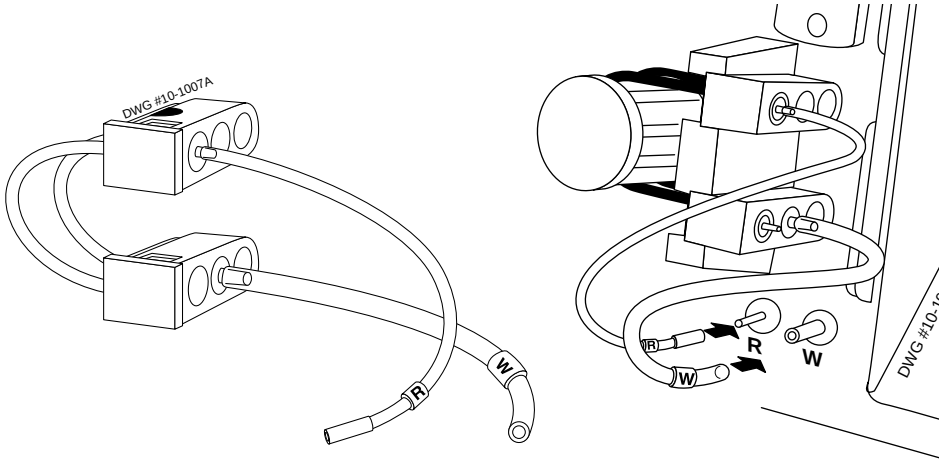


Figure C.5 Installing the Pump Tubing

C.1.5 Reference Line (R-line) Installation

1. Remove the R-line from its packaging.
2. Attach the R-line starting with the pinch valve. (Stretch the elastic segment of the R-line and slide it into the pinch valve.)
3. Connect the top end of the R-line to the R-labeled outlet of the reference electrode.
4. Connect the bottom end to the outside port of the bottom pump manifold.

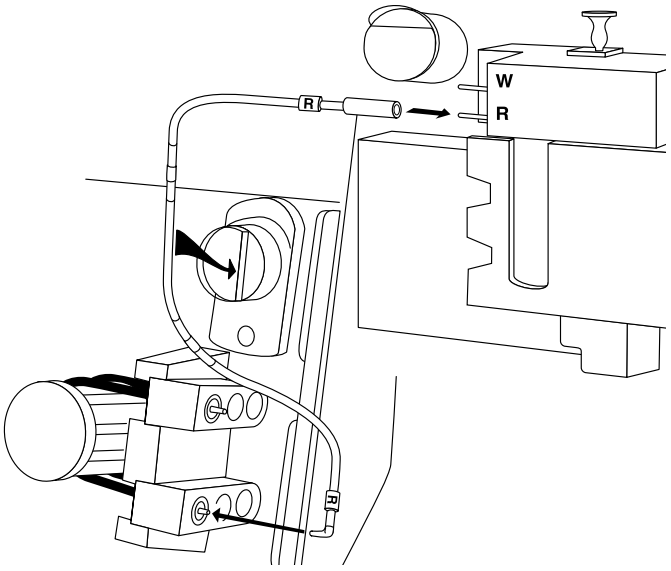


Figure C.6 Installing the R-line

C.1.6 Waste Line (W-line) Installation

1. Remove the W-line from its packaging.
2. Attach the W-line starting with the pinch valve. (Stretch the elastic segment of the W-line and slide it into the pinch valve.)
3. Connect the top end of the W-line to the W-labeled outlet of the reference electrode.
4. Connect the bottom end to the inside port of the top pump manifold. (See Figure C.1 for tubing location.)

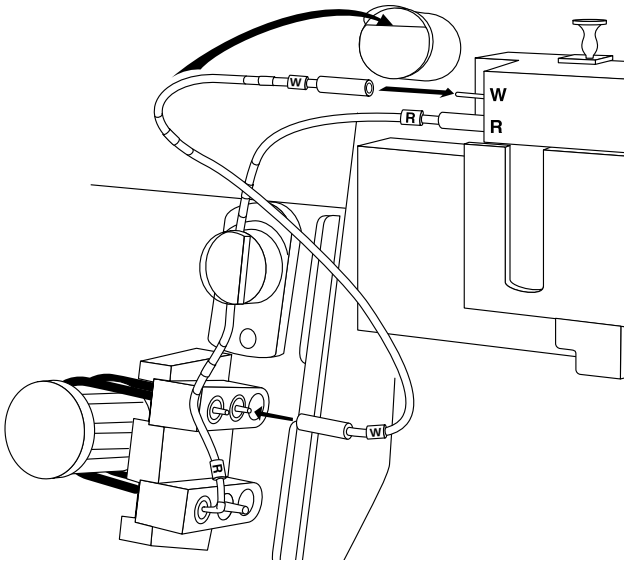


Figure C.7 Installing the W-line

C.1.7 Sodium and pH Sensor Installation

1. Remove the Sodiun and pH sensors from there packaging.
2. Degas the Na^+ sensor.
   a. Hold the Na^+ sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
   b. With the sensor tip still facing downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down.
3. Insert the new Na^+ and pH sensors into the sensor module; slide the sensor body into the sensor module until the sensor clips into place. (Sodium is top left; pH is top right; see Figure C.8.)

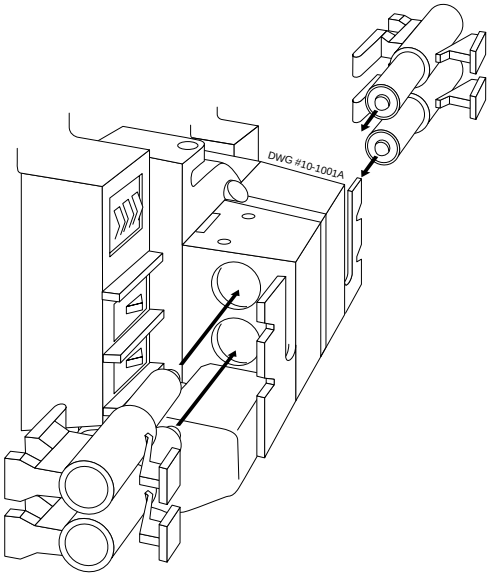


Figure C.8 Installing the Sensors

C.1.8 PO_2 and PCO_2 Sensor installation

1. Remove the PO_2 / PCO_2 sensor from its packaging.
2. Unscrew the protective PO_2 / PCO_2 cap from the PO_2 / PCO_2 body and dispose of it.
3. Take PO_2 / PCO_2 Premembraned Cap that is prefilled with internal filling solution. Shake it gently to ensure that the solution is away from the threaded end and at the membrane end. Unscrew and discard the shipping plug from the cap.
4. Insert the sensor body straight down (vertical position only to ensure no loss of internal filling solution) into the filled cap and screw the cap onto the sensor body.

   NOTE: *The prefilled PO_2 / PCO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the biosensor's performance.*

5. Degas the PO_2 / PCO_2 sensor.
   a. Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
   b. With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.
6. Dry the sensor with a lint-free tissue. Take care not to touch the tip.
7. Insert the new PO_2 / PCO_2 sensor into the sensor module; slide the sensor body into the sensor module until the sensor clips into place. (PO_2 is bottom right; PCO_2 is bottom left; see Figure C.8.)

C.1.9 Probe and Air Detector Installation

1. Verify the air detector, probe, and capillary adapter are installed properly. If not installed, power on the pHOx and continue this procedure.
2. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
3. Press Move Probe (soft key). Open the door.
4. Remove the probe and air detector from their packaging.
5. Place the probe into the air detector and slide both into the sampler assembly.
6. Push the air detector up to lock it in place.
7. Connect the air detector's sample line to the sensor module
8. Install the 2-prong cable of the air detector to the analyzer.
9. Remove the capillary adapter from the reagent pack and gently push it on to the sampler assembly.
10. Press Move probe to move sampler assembly down.
11. Press Cancel. Then press Cancel again to return to the Home screen.

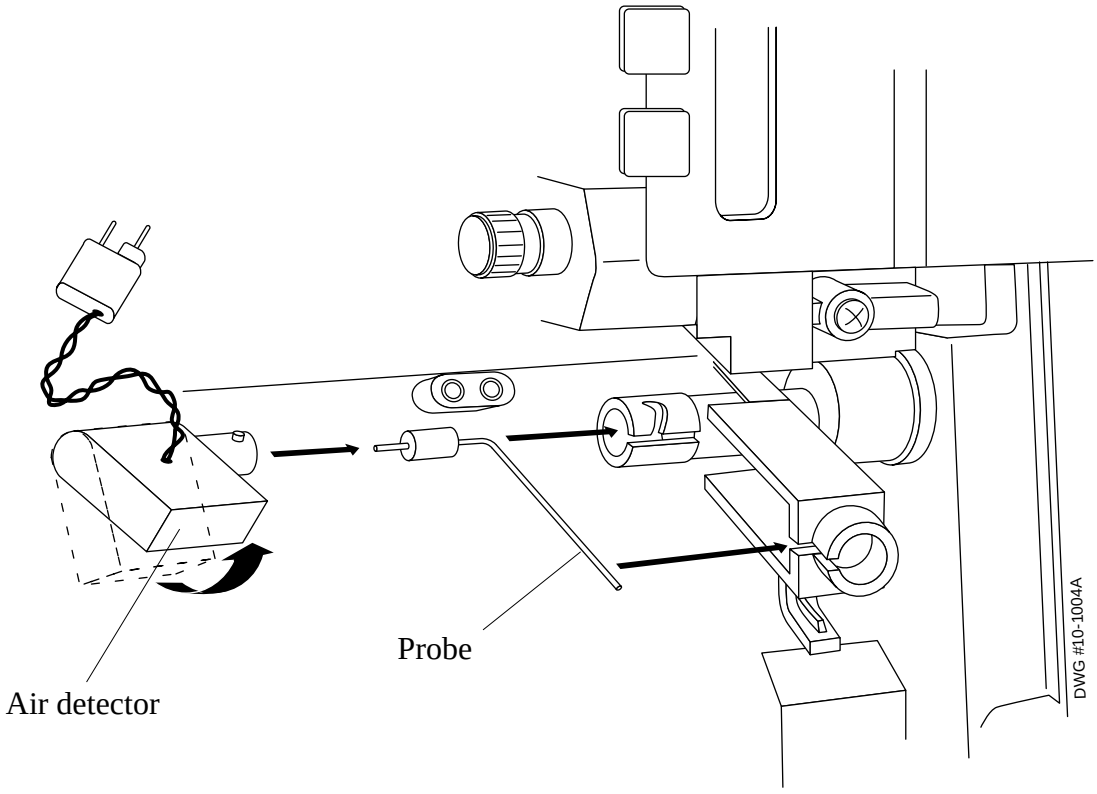


Figure C.9 Installing the Probe and the Air Detector

C.1.10 Reagent Pack Installation

1. Mix the reagent pack by inverting 10 times
2. Open the pHOx door.
3. Insert the pack into the left compartment.
4. Push pack inward (see Figure C.1). Ensure it is seating inside the lip of the analyzer.
5. Power on the pHOx. (Switch is near the power cord.)
6. Validating and Prime reagent pack
    a. Press Menu from the Ready (Home) screen
    b. Arrow down to select Change reagent pack. Press Enter.
    c. Press Prime.
    d. After Priming, a pop-up screen appears to question. Do you want to calibrate? --- Press Yes to Calibrate.

C.1.11 Auto-Cartridge Quality Control Pack Installation

Setup of the controls is necessary to collect data. **If the Lot Number of the new control pack is different, all the previous data for the previous Lot Number will be erased. Remember to print out this data before you change an Auto-Cartridge Control Pack with a different Lot Number.**

> ***NOTE:*** *The analyzer will prompt you with a pop-up screen if the lot number is different, giving you a Warning that all data will be deleted.*

The Control Pack should be changed when the system indicates the pack has expired or is empty. Install the Control Pack as follows:

1. Mix the reagent pack by inverting 10 times
2. Open the pHOx door.
3. Insert the pack into the right compartment.
4. Push pack inward (see Figure C.1). Ensure it is seating inside the lip of the analyzer.
5. From the Operational Menu screen, select Change Pack and press Enter.
6. From the pop-up screen, select Change Control Pack and press Enter.
7. Follow the directions on the screen to install the pack.
8. The control ranges are automatically read from the control pack during the Change Control Pack procedure.

> ***WARNING:*** *When the control pack is removed, keep your fingers and hands away from the back of the pack compartment. There are sharp needles that can cause injury.*

> ***NOTE: The control pack must be replaced through the Change Control Pack option.*** *If you remove and replace a pack (even if it is the same pack) outside these screens, you will not be able to prime the analyzer.*

C.1.12 Calibration

After calibrating the pH, PCO_2, PO_2, Hct, and Na^+ sensors, calibrate the SO_2 and Hb using the external standards.

1. Press Calibrate from the Ready (Home) screen.
2. Arrow down to External two Standard Hb, SO_2% calibration.
3. Press Enter.
4. Enter in the Assay value for Std #1. Press enter.
5. Mix Calibrator #1 by inversion.
6. Open ampule and position the extended probe into the calibrator so that the tip is well covered.
7. Press Continue. When the system signals by an audible alarm, remove the ampule.
8. Press Analyze.
9. Repeat the procedure for Calibrator #2. Enter in the assay value.
10. Mix Calibrator #2 by inversion.
11. Open ampule and position the extended probe into the calibrator so that the tip is well covered.
12. Press Continue. When the system signals by an audible alarm, remove the ampule.
13. Press Analyze.
14. Set up Analyzer to meet the facilities needs.
15. Set up Quality Controls
16. Run quality controls as appropriate for lab/hospital.

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Stat Profile pHOx

WARRANTY REGISTRATION CARD

CUSTOMER COPY

(to be retained by customer)

Unit sold by:

Analyzer Serial No. _____

Delivery Date _____

Distributor _____

Address _____

City _____ State _____ Zip _____

THIS IS YOUR WARRANTY

TO PROTECT YOURSELF - MAIL IN FACTORY COPY

RETAIN THIS COPY IN YOUR FILES

Cut and detach before mailing

WARRANTY REGISTRATION CARD Stat Profile pHOx

FACTORY COPY

(to be sent to Waltham, Massachusetts)

Analyzer Serial No. _____

Delivery Date _____

Operator name _____

Laboratory _____

Company or institution _____

Address _____ Telephone No. ( ) _____

City _____ State _____ Zip _____

Distributor purchased from: _____

Distributor Location: City _____ State _____ Zip _____

Installed by: _____ Date _____

_____

(Customer Signature)

NOVA BIOMEDICAL
CUSTOMER'S WARRANTY
STAT PROFILE pHOx ELECTROLYTE ANALYZER

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, breakage, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative, or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. **All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure.** Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. All requests for service outside Nova's principal hours of operation will be rendered at the prevailing weekend/holiday rates after receipt of an authorized purchase order. Contact Nova for specific information.

The following exceptions apply:

1. The sodium electrode is warranted for one (1) month pH, PCO_2, PO_2, and reference electrodes are warranted for six (6) months from the date of installation, provided they are stored at room temperature and placed into service prior to the use before date on the packaging. In the event that an electrode does not meet that use life, then Nova Biomedical will replace that electrode at no charge under this warranty. This warranty is invalid under the conditions specified after item 3.
2. Consumable items, including the reagent pack, calibration gases, replaceable membranes, tubing and tubing harnesses, electrolyte solutions, external standards, and septum assemblies are warranted to be free of defects at time of installation. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing. This warranty is invalid under the conditions specified after item 3.
3. Freight is paid by the customer.

The above warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows:
   Nova Biomedical will not be responsible for any warranties on electrodes, tubing, probes, septa, or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as shortened electrode and septa life, electrode membrane damage, electrode drift, erratic analytical results, and inaccurate instrument performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

IN ORDER FOR THE WARRANTY TO BE EFFECTIVE, THE WARRANTY CARD MUST BE SENT TO NOVA BIOMEDICAL, 200 PROSPECT STREET, WALTHAM, MA 02454-9141, USA.

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 47966 WALTHAM, MA

POSTAGE WILL BE PAID BY ADDRESSEE

Nova Biomedical
200 PROSPECT STREET
PO BOX 9141
WALTHAM, MA 02454-9141

INSTRUCTIONS

1. FILL OUT COMPLETELY.
2. In order for the Warranty to be effective, the warranty cards must be signed and dated as of the date of delivery and sent to NOVA BIOMEDICAL, WALTHAM, MASSACHUSETTS.
3. Retain one card for your files.

1.3 The Sample

Sodium or lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes can be used on the Stat Profile pHOx Analyzer. The sample size is 70 µL for normal mode and 40 µL for micro mode (blood gases only).

1.3.1 Handling Requirements

Correct sample handling is critical to ensure that the blood gas values obtained accurately reflect the *in vivo* state. Ensure that all samples have been obtained and stored following consistent, clinically accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample within 15 minutes for blood gases. Storing samples on ice is not recommended. Using iced samples may elevate the PO_2 result.[1]

1. National Committee for Clinical Laboratory Standards. *Considerations in the Simultaneous Measurement of Blood Gases, Electrolytes, and Related Analytes in Whole Blood; Proposed Guideline.* NCCLS Document C32-P. Vol. 13, No. 17.

1.3.2 Acceptable Anticoagulants

Sodium and lithium heparin are the recommended anticoagulants for use with the Stat Profile pHOx Analyzer. EDTA, citrate, oxalate, or sodium fluoride are not recommended for use.
Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, heparin concentrations of 20 I.U. per mL to over 100 I.U. per mL may be obtained. Liquid heparin when present in excess may cause errors by dilution in pH, PCO_2, and PO_2.
Our experience suggests that lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable in the critical care laboratory. Stat Profile pHOx Analyzer users should take careful note of these considerations when establishing reference intervals and interpreting results.

3.12 Auto-Cartridge QC

Nova Biomedical's Auto-Cartridge QC is a total automated control system contained within a single on-board reagent cartridge. This system allows any level of quality control to be run at any time: either on a programmed schedule or on demand. The Auto-Cartridge QC system reduces costs by eliminating the time and labor required to manually perform quality control.

Each Nova Auto-Cartridge contains 3 levels of blood gas controls, 2 levels of hematocrit, SO_2%, and hemoglobin controls, plus software that automates running controls and storing quality control data. When the cartridge is installed, all quality control target ranges, lot code, and expiration date information is automatically downloaded to the analyzer. The user then programs the pHOx Analyzer to automatically analyze up to 3 quality control levels, 3 times per day (a total of 9 analyses per day). If any analyte is outside the target range, it is automatically reanalyzed. If a control value remains out of range, the user is notified.

All quality control data is automatically stored. Daily and cumulative statistical reports and Levey-Jennings graphs can be printed at any time. This automation assures that quality control is always performed accurately and on schedule, thereby guaranteeing regulatory compliance.-

3.13 Movement Of Fluids

To begin an analysis, press the Capillary or Syringe key to move the sampler to either the capillary or syringe position. Present the sample to the probe and press either Aspirate Normal or Aspirate Micro (soft keys). The Aspirate Normal soft key allows for the aspiration of 70 µL of sample, and the Aspirate Micro soft key allows for the aspiration of 40 µL of sample. The sample is aspirated by the peristaltic pump until the leading edge is detected by either the 40 µL or 70 µL air detector. After the aspiration is completed, there is an audible beep and a pop-up display that prompts you to press Analyze after removing the syringe or capillary. The sample is advanced until the leading edge is properly located in front of the electrodes. Once all measurements have been completed, the sample is pumped to the waste and the flow path is washed.

Acceptable Samples:	Whole Blood (heparinized)
Measuring Technology:	Ion Selective Electrodes (Na^+, pH, PCO_2) Amperometry (PO_2) Conductivity (Hematocrit/Hemoglobin) Reflectance Photometry (Oxygen Saturation/Hemoglobin)

Analysis Rate:

Stat Analysis Time	Throughput Time
45 seconds	60 seconds

Sample Volume: 40 microliters whole blood micro sample for blood gases
70 microliters whole blood sample size for full panel

Barometer: 400 - 800 ±1 mmHg, accurate to 1.5 mmHg

Slope Limits:

pH	9.1 - 11.6
PO_2	-15.0 - (-1.6)
PCO_2	7.9 - 12.6
Hct	12.0 - 50.0
Na^+	8.3 - 12.0
SO_2	6.9 - 18.2

Slope and Offset Limits:

	Slope	Offset
pH	N/A	lower -0.1 upper 0.1
PCO_2	lower 0.80 upper 1.20	lower -10.0 upper 10.0
PO_2	lower 0.90 upper 1.1	lower -20.0 upper 20.0
SO_2	lower 0.90 upper 1.1	N/A
Hct	lower 0.80 upper 1.20	lower -10.0 upper 10.0
Hb	lower 0.9 upper 1.1	lower -2.0 upper 2.0

*Specifications are subject to change.